APPLYING HUMAN FACTORS RESEARCH TO ELECTRONIC PRESCRIBING CLINICAL DECISION SUPPORT

By

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LIST OF SYMBOLS AND ABBREVIATIONS

ADE	Adverse Drug Event
CPOE	computerized physician order entry
EHR	Electronic Health Record
e-Rx	Electronic Prescribing
DAM	Drug Allergy Conflicts
DDCM	Disease Contraindications
DDIM	Drug-Drug Interactions
DFIM	Drug-Food Interaction
DI	Duplicate Ingredient
DOSE	Dose Range Checking
DT	Duplication of Therapy
FDB	First Databank
FR	Frequency
GERI	Geriatric Precautions
LACT	Lactation Precautions
MONO	Monograph
PEDI	Pediatric Precautions
PREG	Pregnancy Precautions
RxStar	VUMC outpatient e-Rx system
SE	Strength of Evidence
SV	Severity

SIDE	Side Effects
StarPanel	VUMC EHR system
TVC	The Vanderbilt Clinics
VUMC	Vanderbilt University Medival Center

CHAPTER I

INTRODUCTION

Clinical decision support (CDS) in electronic prescribing (e-Rx) systems can improve patient safety and quality of care (1, 2). Despite the availability of drug information knowledgebases and decision support modules, systems containing this functionality often have it disabled or customized to minimize irrelevant or insignificant alerts, due to concerns about alert fatigue, i.e., decreasing the "attention cost" of alerts (3). We postulate that novel user interfaces may decrease the "attention cost" of alerts, as has been shown in inpatient CPOE (1). This study aimed to explore alternative approaches to display alerts, and examine whether and how human factors based interface design can be used to improve signal detection from noisy data (alerts and reminders) in an existing e-prescribing system

CHAPTER II

BACKGROUND

Introduction

The calls for universal electronic prescribing (e-Rx) are louder than ever (1, 2, 4). Actions should be taken to encourage physicians' adoption. Current estimates suggest that between 5% and 18% of clinicians use e-Rx (2, 4). However, despite increasing calls for the use of electronic prescribing by groups such as the Institute of Medicine (5) and the eHealth Initiative (2, 4), e-prescribing adoption has not reached the levels called for by the federal government (6). It is widely believed that poor design of clinical decision support in these systems is a large part of the barrier to adoption (2, 4). Issues such as a large number of alerts leading to ignoring important alerts - called "alert fatigue", and user interfaces that disrupt the work process and require inordinate time to comprehend (i.e., increasing the "attention cost" of the prescribing process) are among the challenges yet to be overcome. The goal of this project is to explore the potential of novel user interface designs to improve the presentation and comprehension of clinical decision support during e-prescribing.

E-Prescribing

In the United States, prescription medications are central to health care. According to the eHealth Initiative 2004 formal report (2, 4), more than 3 billions prescriptions are written annually, accounting for 13% of health care expenditures and being used by 65% of the U.S. population. The erroneous use of prescription medications (such as incorrect dosages, drug-drug interactions or

drug-allergy interactions) is common and often results in patient injuries. In general, injuries from medications are termed adverse drug events (ADEs). A study found that 4.3% of patients experienced ADEs, 83% of which resulted from outpatient prescriptions. Another study of 62,216 emergency department visits found that 1.7% of visits resulted from outpatient ADEs. A meta-analysis of 36 studies concluded that 5% of hospital admissions resulted from outpatient ADEs and only 23% were due to patient errors (3). Center for IT Leadership (CITL) 's report on ambulatory setting CPOE systems estimated 8 millions ADEs in U.S. per year; more than 3 millions were preventable; this is equal to 38 ADEs per provider-year and on average 14 were preventable per provider-year (7).

Electronic prescribing, often abbreviated as e-prescribing or e-Rx, is "computer-based support for the creation, transmission, dispensing, and monitoring of pharmacological therapies" (1). e-Rx is the use of computing devices (clinical workstation, personal computer, or handheld devices) and drug information knowledgebases to enter, modify, review, output or communicate drug prescriptions (2). e-Rx is a form of computerized physician order entry (CPOE) and is available in a variety of graduated levels ranging from basic prescription entry to linked additional electronic drug references, to advanced integration into an EHR (2, 4, 7). Theoretically, e-Rx with integrated decision support can reduce medication errors and ADEs, improve health care efficiency and patient safety (2-4).

Clinical Decision Support and E-Prescribing

In healthcare areas, clinical decision support has been defined somewhat differently by different authors or groups (8-13). Teich, et, al. defined "clinical decision support" in CPOE/e-Rx systems as "'providing clinicians or patients with clinical knowledge and patient-related information,

intelligently filtered and presented at appropriate times, to enhance patient care'" (10). This functional term includes not only the familiar reactive alerts and reminders (such as alerts for drug allergy conflicts and drug–drug interactions), but also many other intervention types, including pick lists, structural order sets, medication reference information for prescribers and patients, and any other guideline support that can promote safety, education, workflow improvement, and improved quality of care.

Clinical drug alert/reminder is a form of clinical decision support. Clinical alert/reminder systems have been the central tools used with e-Rx systems. These systems use computer-generated messages that notify prescribers when their actions may be potentially unsafe. Typically, e-Rx systems provide decision support in many areas, including (2, 7, 9, 10):

- Drug-allergy interaction
- Drug-drug interaction
- Drug-disease interaction
- Drug-lab interaction
- Drug-food interaction
- Drug-herbal remedy/vitamin interaction
- Duplicate ingredient
- Recommended dosing limits including patient-specific limits on total dose, dose rate, etc.
- Geriatric precaution
- Lactation precaution
- Pediatric precaution
- Pregnancy precaution
- Structural order sets

- Drug reference information including formulary information, insurance information, cost, generic alternatives
- National/institutional/departmental guidelines that can promote safety, education, workflow improvement, communication between different stakeholders, and improved quality of care, etc.

In general, drug alerts/reminders are triggered based on pre-defined rules from CDS modules embedded in or connected to e-Rx systems. e-Rx writing tools promise to deliver safe and effective care, in part through their ability to influence clinician decision-making by displaying patient-specific alerts. They also can help make clinical data readily available and reduce the time a prescriber needs to spend accessing data – giving a prescriber more time with the patient, and potentially allowing the prescriber to provide better care.

Barriers to e-Prescribing Adoption

Despite the availability of commercial drug information knowledgebases and CDS modules, users often disable this functionality. The reasons for this appear to fall within two main themes: the perceived insignificance of the alerts; and the poor integration of alerts into workflow(2-4, 14, 15).. Each of these barriers will be discussed below.

Signal-to-Noise issues

Issues of workflow integration are made more significant when the drug alerts are not considered important. Numerous studies have demonstrated extremely high override rates, far and above the probably of relevance proposed by Johnson and Grundmeier (16). For example, Payne, et al., studied characteristics and clinicians' override of 42,641 prescription orders and about 4500

safety checks associated with those prescriptions from a practitioner order entry system in a VA hospital (17). They discovered an 88% override rate for drug interaction alerts and a 69% override rate for drug-allergy interaction alerts. Isaac, et al., in a recently published study, looked at 233,537 medication safety alerts associated with 3.5 million electronic prescriptions generated by 2,872 physicians at community-based outpatient practices in Massachusetts, New Jersey and Pennsylvania (18). They found that, of those 233,537 alerts, 98.6% were for a potential interaction with a drug being taken by a patient, but physicians overrode 93.4% of the drug interactions and 77% of the drug allergy alerts.

The high override rate suggests that most prescribers do not find currently implemented, intrusive alerts valuable, and that major changes are needed to improve the usefulness of electronic medication alerts. This was proposed by Weingart, in his study of physicians' override rates for 3,481 drug allergy and drug interaction alerts in primary care (19). Physicians overrode the majority of alerts for drug allergies (91.2% override rate) and drug interactions (89.4% override rate), and no significant number of ADEs occurred, suggesting that the threshold for alerting was set too low or that the signal-to-noise rate of drug alerts was low (or both.) They recommended, for example, that e-Rx applications should suppress alerts for renewals of medication combinations that patients currently tolerate.

Workflow Integration Issues

Studies have previously demonstrated that CPOE success depends upon several factors, including clinicians' access to CPOE systems that are integrated into a uniform information workflow (1, 9, 20). Miller and colleagues(9) summarized multiple mechanisms for delivering decision support within the context of CPOE systems. Three important axes were identified for

delivering decision support content: the role for decision support, the time to intervene, and the method to intervene. According to these studies, decision support may be integrated into the workflow in 2 presentations styles. Those styles include:

1. Intrusive presentation. An example of intrusive presentation is shown in Figure 1. With this type of drug alert presentation, the prescriber is required to generate a response before continuing the ordering process.

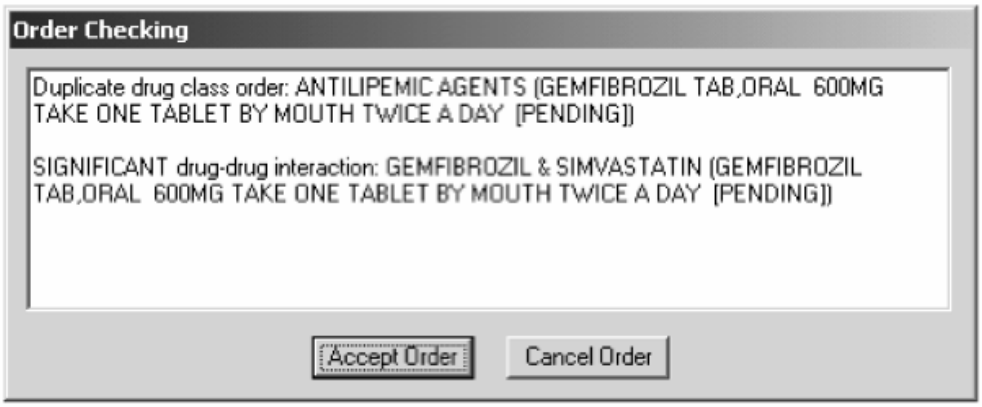


Figure 1: Intrusive pop-up window text to deliver drug alert (21)

2. Actionable presentation. An example of actionable presentation is shown in Figure 2. This type of drug alert presentation allows the prescriber to consider and choose (or not) the recommended action within the alert window itself.

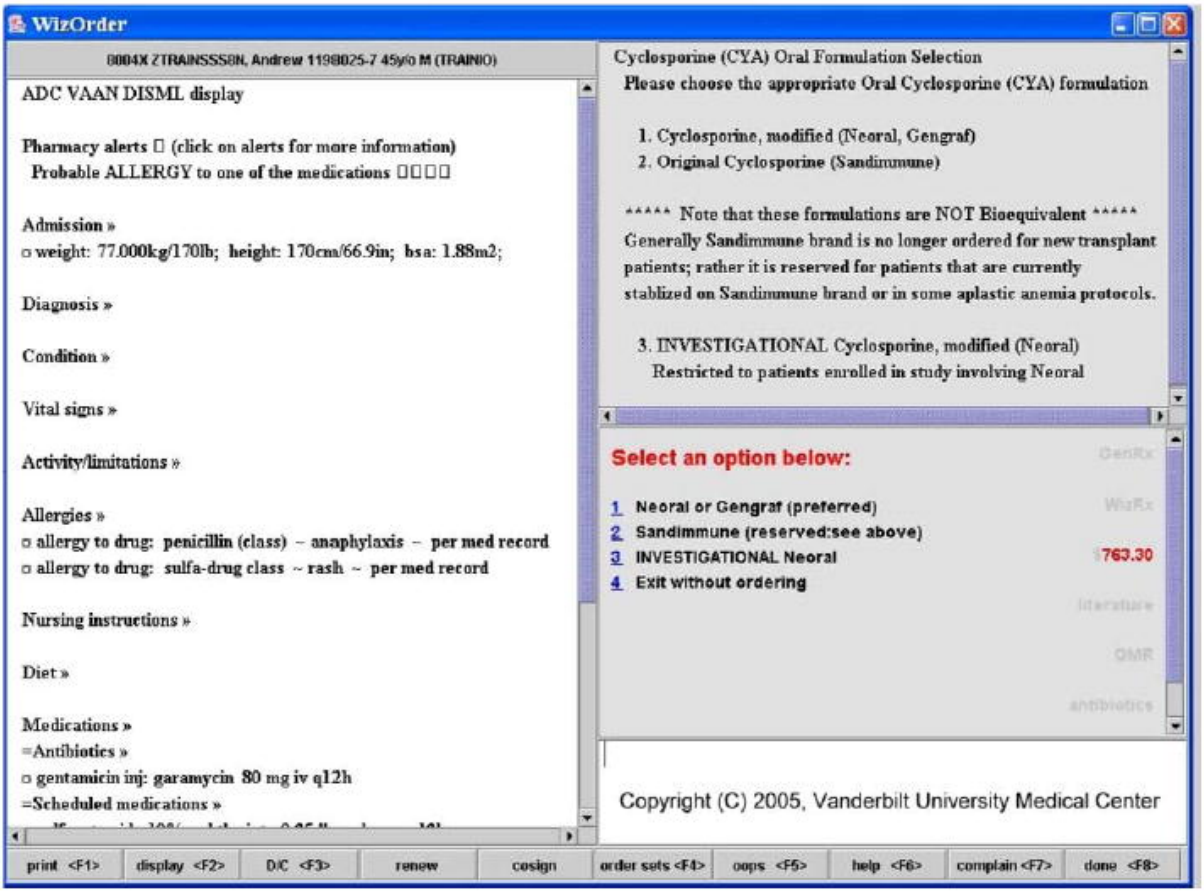


Figure 2: Actionable options in subpane to deliver guidelines for best practice (9)

A more complex form of decision support may combine different presentation styles together and integrate patient-specific information (patient demographics, diagnosis, laboratory results, active orders, guidelines, protocols, etc.) (9). Depending on the type and severity of the alert, one or another presentation styles may be most appropriate. A study by Rosenbloom and Miller (20) evaluated the relationship between physicians' override rates and different drug alert presentation methods. The use of an intrusive presentation method, while providing clinically important information, did so at a significant workflow cost to prescribers. A "pop-up" alert in a separate user

interface window was viewed by users as disruptive, and should be reserved for only the most severe clinical indications.

A Case Report: First Databank Commercial Knowledgebase

To understand the volume of clinical drug alerts generated by commercial drug information knowledgebases, a prototype e-Rx application was developed using a connection to the First DataBank® (FDB) drug information knowledgebases. This prototype allowed the user to screen prescribed medications for 13 decision support modules including Drug Allergy Conflicts (DAM), Disease Contraindications (DDCM), Drug-Drug Interactions (DDIM), Drug-Food Interaction (DFIM), Duplicate Ingredient (DI), Dose Range Checking (DOSE), Duplication of Therapy (DT), Geriatric Precautions (GERI), Lactation Precautions (LACT), Pediatric Precautions (PEDI), Pregnancy Precautions (PREG) and Side Effects (SIDE). Figure 3 shows the interface of prototype application. In our feasibility tests, a mock-up patient profile with only 2 diagnosis, 2 allergies, and 10 medications triggered 49 clinical drug alerts with the 5 screening modules in the First DataBank® drug information knowledgebases (Nov. 2003 version). Similarly, a mock-up patient profile with 6 diagnosis, 2 allergies, and 10 medications triggered more than 150 clinical drug alerts if 9 screening modules were selected. According to domain expert clinicians, many of these drug alerts were of low clinical significance. We concluded that the number of alerts triggered by this commercial drug information knowledgebases was considered unbearable therefore would be treated as "noise" by prescribers. Moreover, given the large number of alerts, the few clinically significant alerts are more likely to be overlooked (a problem of low signal-to-noise ratio).

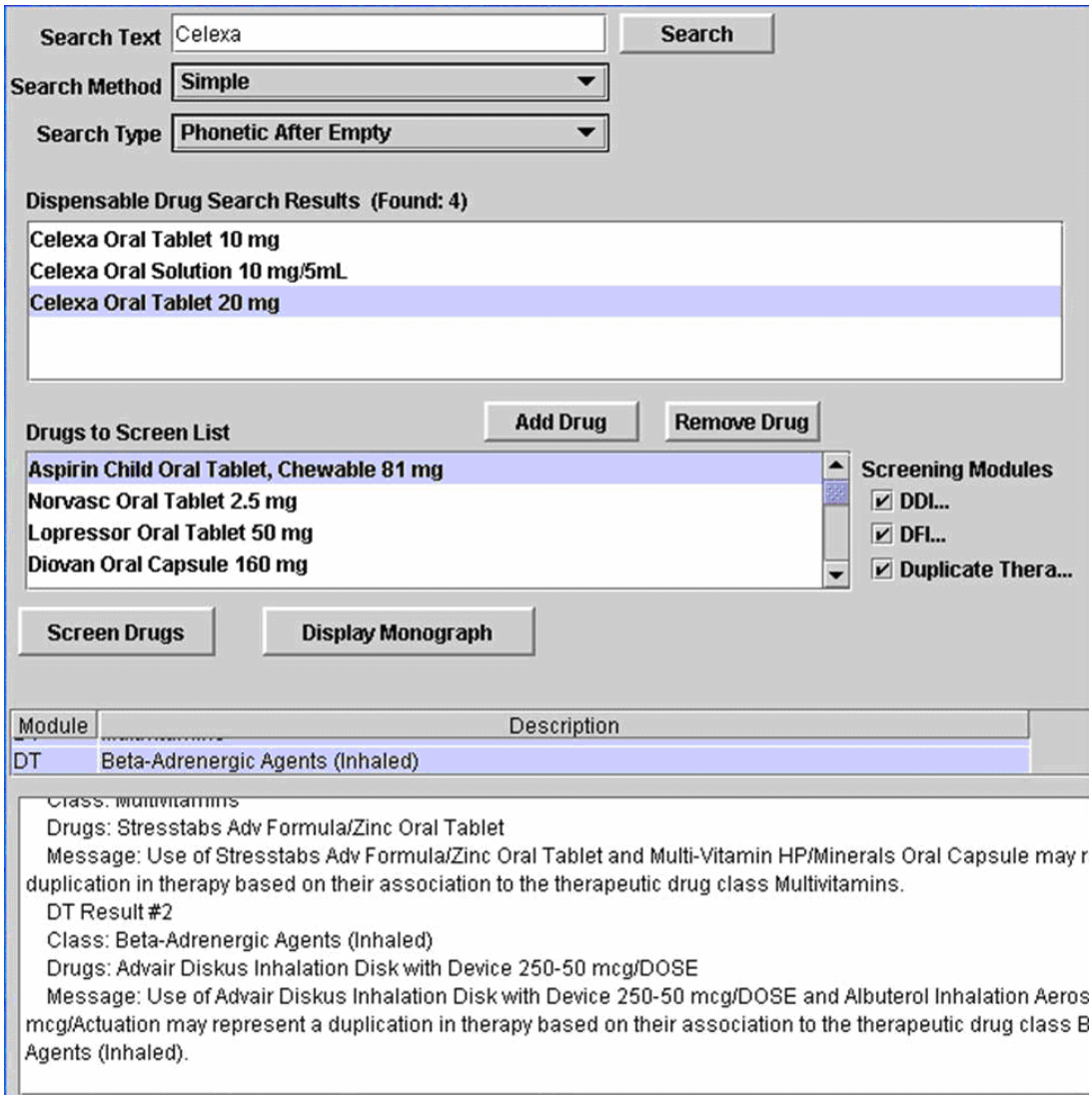


Figure 3: The interface of prototype e-Rx application

The role of Human Factors Research

Many authors (2-4, 14, 22-26) list the major usability guidelines for achieving a successful e-Rx product. Although all of usability guidelines listed in the literature may be important to effective design, the scope of proposed study and task requirements compelled us to focus on those deemed critical to the study objectives (described below):

1. Efficiency. Physicians are generally under significant fine pressure and want to spend less time accessing data and more time with their patients. In reality, it is difficult to convince a physician that clicking through menus and choosing from options is more efficient than simply scribbling some words on a pad of paper. However, through our literature review and contextual inquiries, we found that the majority of physicians' time is not actually spent writing the prescription itself, but rather on researching information in order to write a prescription and maintaining the prescription record. Therefore, a design that reduces information retrieval while not impacting prescription writing time is essential to a successful product.

2. Information density. There is a trade-off between a design that does not crowd too much information per screen (excessive information density) and the need to display as much information as needed on one screen. Physicians want a comprehensive system with ready access to key information. They prefer an effective but simple user interface to minimize cognitive burden and to reduce the risks of errors. The e-Rx systems can predispose to use errors, such as selecting a sound alike but wrong medication from a pick list or prescribing for the wrong patient due to a failure to exit the previous patient's record (25). For high volumes of information such as comprehensive drug references, it may be better to split up the information in a logical manner, such as general information, drug conflicts, and drug dosages and display them in different areas of the screen.

3. Freedom of user control. It may be better to let the users decide what kind of information they need most. Users could select different decision support modules and decide how to display various types of clinical alerts on the screen. Moreover, on every page of the prescription writing process, it may be a good idea to provide the option to cancel the current prescription that a physician is writing, or provide an alternative suggestion for the replacement. This feature will provide more flexibility for the e-Rx users (2, 4, 25).

4. User-centered Design (27). It is well known that a commercial drug information knowledgebase can provide comprehensive drug reference but generates low signal-to-noise information, as described above. Visualization and evaluation techniques are available to facilitate the design of user interfaces, and have demonstrated an ability to improve users access to and understanding of large amounts of information (28-30). In addition, careful use of intrusive delivery methods like "pop-up" window, and less intrusive delivery methods like in-line "incidental display of relevant information", should be better aligned with the types of alerts presented to prescribers (1, 9). Of note, there is virtually no literature examining the presentation and prioritization of multiple drug alerts. Given the massive number of drug alerts that commercial drug information knowledgebases can produce the low signal-to-noise ratio of these alerts, it is very important to assess how different alerting interfaces can impact delivery and organization of multiple drug alerts in an e-Rx application. This assessment is the goal of this study.

In this study, we only focused on user interface design and evaluation for outpatient e-Rx using a typical desktop PC-based system. The study may also provide information applicable to the use of PDA-based systems, which have better mobile performance but are less functional than desktop PC platforms.

CHAPTER III

INTERFACE DEVELOPMENT AND EXPERT REVIEW

Introduction

In the previous chapters, I noted the challenge of low signal-to-high noise ratio of medication alerts and the potential for attention to usability factors to improve e-Rx systems. In particular, specific aspects of usability such as efficiency, error presentation, information density, and freedom of user control may be important to explore as we seek to improve the delivery of medication alerts.

We postulate that novel user interfaces may be required to decrease the attention cost of alerts in the outpatient setting. In this study, attention cost is defined as prescriber's effort or amount of activity to get the e-Rx work done accurately and completely. At least one inpatient computerized physician ordering entry system had focused on a similar approach with good results (1).

This study was designed to explore alternative approaches for displaying clinical drug alerts in an outpatient e-Rx system. The study was broken into three specific aims. This chapter will explore the process and results of the First Aim: Using a user-centered design, iteratively build, evaluate and refine a series of user interfaces to display alerts based on available human-computer interface.

Methods

Four methods were employed to develop these candidate user interfaces. First, existing

literature about human-computer interfaces was explored to discover specific user interface approaches that have been developed for multi-dimensionality alerting. PubMed database, ACM (Association for Computing Machinery) digital database and SIGCHI (Special Interest Group on Computer-Human Interaction) database were searched. The combination of the terms used included: (electronic prescription OR e-prescription OR e-Rx) AND (system OR model); (electronic prescription OR e-prescription OR e-Rx) AND (user interface OR interface design); (drug alert OR medication alert OR drug reminder) AND (user interface OR interface design OR presentation); (alert OR reminder) AND (information visualization). We briefly reviewed the abstracts of relevant articles and retrieved the full-text articles that might contribute to developing the drug alert interface in an e-Rx system.

Second, we completed a process called information mapping based on common information axes available in existing drug information knowledgebases. Information mapping is a scientific methodology used to divide and label information for easy comprehension, use, and recall (31). In the context of this study, we mapped the drug alert attributes (category of alert, severity, frequency, strength of evidence, etc.) to different metaphors (color, text, icon and shape) to ensure that the drug alert content could be readily captured and comprehended by clinician prescribers.

Third, we used the mapping results to construct a prototype clinical decision support interface designed to present multiple drug alerts generated from commercial First DataBank® drug information knowledgebases. This application was developed using Java/Oracle programming, and allowed us to explore knowledgebase output with predefined complex cases; the prescriber could explore different alert presentation formats that present the same set of medication alerts. I used our 4 interface concepts to construct the prototype:

- Interface concept #1: text based alert presentation

- Interface concept #3: tree based alert presentation
- Interface concept #4: tree-dashboard based alert presentation
- Interface concept #2: thermometer based alert presentation

Each of these is more fully described later in the results section.

Finally, to access overall clinician perception about the drug alert presentation interfaces, we conducted an Expert Review. This study consisted of presenting screen snapshots from our prototype to a group of prescribers, based on patient scenarios tested during the third phase of this aim. We used a convenience sample of 6 expert reviewers (32), consisting of faculty/fellow members from the Department of Biomedical Informatics, VUMC. All participants were active practitioners with at least 2 years experience working with EHR and e-Rx systems. For this final phase, the researcher met individually with each domain expert and used a think-aloud method while asking the experts a series of questions (33). For each interface, two types of questions were asked:

1. You are prescribing a medication and are presented with the display above. What does this display mean? Choose the most precise answer.
    - The patient has an allergy to a medication
    - The prescriber is trying to prescribe a medication to which the patient may be allergic.
    - The patient is receiving an overdose of Lortab

OR

2. You are prescribing a medication and are presented with the display above.
    - Describe what is happening in this picture?
    - What do the different elements on this page mean?

Each participant received a 14-page storyboard, including cover page, tutorial and snapshots of the e-Rx application (4 interface concepts, 2 snapshot pictures each, randomly ordered). A copy of the storyboard is provided in Appendix A. During the interview, the domain experts were asked to review and rank order the 4 interfaces in terms of clarity and ease of use. The participants were also asked to comment on any issues related to multiple drug alert presentation.

Data Analysis

We analyzed the survey questionnaires to assess accuracy of the interpretation (i.e., the fact that a Lortab-associated drug-food alert, not a drug-allergy alert, was delivered to screen), in addition to a subjective assessment of the interface to evaluate if the alerts were easy to interpret, comprehensive, efficient, and discriminating (easy to catch critical information).

Results

Alternative approaches to display drug alerts

Initial literature and computer-human interface review identified a series of interface approaches. Four potential interface approaches appeared to show promise - ScrollText, Tree, TreeDashboard, and Thermometer - for information mapping and further application implementation (described below in details). Screen views of these approaches are shown in Figure 4.

ScrollText is a user interface that presents drug alert information in plain text format and in an essentially linear way (34). The presciber can vertically scroll the text back-and-forth to locate various indicators. "Scrolling", as such, does not change the layout of the text or metaphors, but more or less facilitates the navigation of various drug alerts.

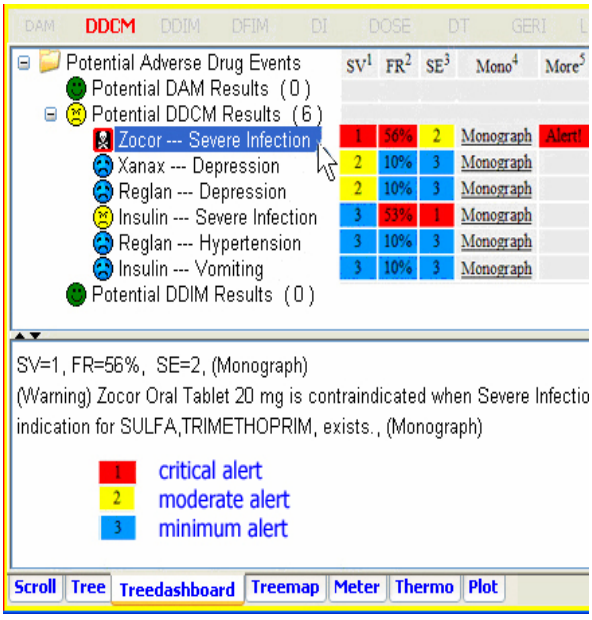
Tree is a user interface that presents drug alert information hierarchically (35). The hierarchy level of various drug alerts is shown by indentation on the left side of the Tree nodes. The tree is a collection of one or more nodes. Each node represents a screening module, e.g. drug-drug interaction screening, drug-disease ccontraindication screening. Each node is the parent of zero or more children, which are also nodes corresponding to multiple drug alerts retrieved from a certain screening module. A tree can be expanded (expanded nodes show their children) or collapsed (children are hidden). The way in which a collapsed or expanded node is displayed depends on definitive filtering rules.

TreeDashboard is a user interface that, at the cost of some visual and programming complexity, shows the hierarchy of items, plus a matrix of additional data or item attributes in one unified structure. In this study, TreeDashboard-View assembles the information from multiple components into a unified display and presents multiple drug alert information in a way that is easy to read, and easy to interact during e-Rx. It also allows the prescriber to see a summary of various indicators. TreeDashboard is based on the concept of TreeTable (35), but it is more interactive in the way that the end users' decisions, preferences and needs could be executed while the user is interacting with various indicators.

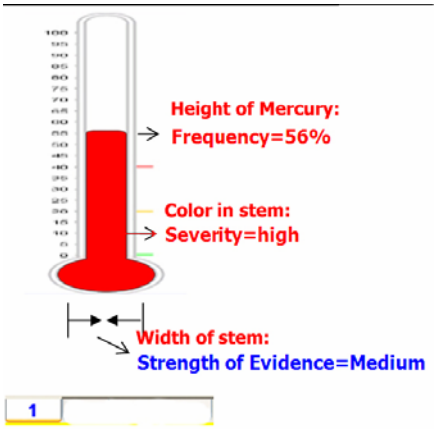
Thermometer is a user interface that presents multiple drug alerts in visualization of various thermometers (36, 37). Clinicians are all familiar with thermometers and may be more sensitive than anyone else on the changes of a thermometer metaphor. In this implementation, each drug alert was represented by a thermometer metaphor; the drug alert attributes was presented by thermometer's characteristics: mercury's height, stem's colour, thermometer's width, etc.

ScrollText-View

Tree-View



TreeDashboard-View



Thermometer-View

Figure 4: Drug alert presentation methods - Scrolltext, Tree, TreeDashboard, Thermometer-View

Information Mapping

Five drug alert attributes were included in our information mapping and are shown in Table 1. A sixth attribute (strength of evidence) was available in some knowledgebases and was included because of its potential value to clinicians. The mappings of the six attributes to our four representative interfaces are shown in Table 2. The final prototypes for each of 4 interface approaches are displayed in Figure 4.

Attribute	Description
Type	Category of drug alert, based on various screening modules defined in FDB drug information knowledgebases, consisting of drug-drug, drug-food, drug-disease, drug-indication alerts, and dosing, lactation, pediatric, pregnancy, side effect and DT warnings.
Severity	Severity of the interaction or contraindication (retrieved from FDB drug information knowledgebases)
Frequency	Frequency/prevalence of the interaction or contraindication (retrieved from FDB drug information knowledgebases)
Strength of evidence	Strength of evidence supporting the warning (FAKE DATA—shown for demonstration purposes only)
Description	Description of the interaction found
MONO	Monograph, which includes detailed information on drug's adverse reactions, contraindications, pharmacokinetics as well as related drug monograph topics (retrieved from FDB drug information knowledgebases if there exists)

Table 1: Description of drug alert attributes

	Scrolltext-View	Tree-View	TreeDashboard-View	Thermometer-View
Category of Alert	Each subpane contains one type of alerts	Each tree node contains one type of alerts	Each tree note contains one type of alerts	Text around thermometer
Severity	Colored text in the result panel	Face icon Red: Severe Yellow: Moderate severe Blue: Mild severe Green: Minimal (OK) White: None	Face icon leaf: Red: Severe Yellow: Moderate severe Blue: Mild severe Green: Minimal (OK) White: None	Liquid color Red: Severe Yellow: Moderate severe Blue: Mild severe Green: Minimal (OK) White: None
Frequency	Colored text in the result panel	Number after face icon in each tree leaf	Number after face icon in each leaf OR Number in column	Height/color of liquid in thermometer stem
Strength of Evidence	Colored text in the result panel	Number after face icon in each leaf	Number after face icon in each leaf OR Number in column	Number/color in thermometer bulb; or height/color of liquid of thermometer stem
Brief Text (Title)	Colored text in the result panel	Text in each tree leaf	Text in each tree leaf	Text in or around thermometer
Detail Text	Colored text in the result panel	Text in the subpane	Text in the subpane	Text around thermometer or in subpane
Alternatives	Colored text in the result panel with links	Text in the subpane with links	Text in the subpane with links	Text around the thermometer or in subpane with links
Navigation	Tabs, Scroll panel, mouse cursor, Keyboard	Tabs, mouse cursor, keyboard, subpane	Tabs, mouse cursor, keyboard, subpane	Tabs, mouse cursor, keyboard

Table 2: Drug alert attributes that have been mapped to each potential interface approach

Expert Review and Evaluation

A prototype e-Rx application was then programmed using Java and Oracle, implementing decision support using all 13 screening modules provided by commercial FDB drug information knowledgebases. Figure 5 displays the screen snapshot of e-Rx prototype application. The user interface of e-Rx application was divided into two parts: a Rx writer on the left, and a clinic alert collector on the right. After the user inputs new medication(s) or selects one of several predefined complex cases from the bottom left side of screen, and clicks the "Check ADE" button (cursor arrow in Figure 5), the clinical drug alert information is displayed on the right side of screen.

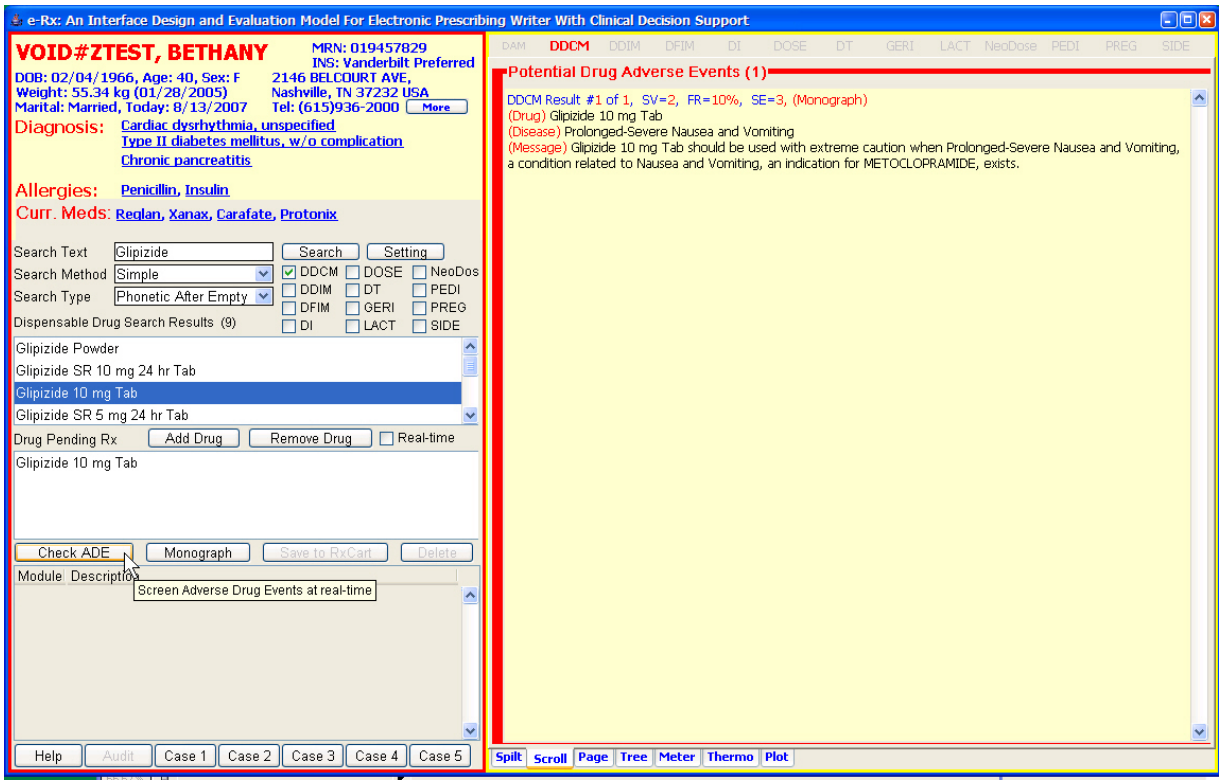


Figure 5: the screen snapshot of e-Rx prototype application

Six domain experts we invited all agreed to participate the study. Participants received a 14-page storyboard, including cover page, tutorial and snapshots of the e-Rx application (4 interface concepts, 2 snapshot pictures each, randomly ordered). All subjects reviewed all 4 drug alert presentation interfaces and then filled out the questionnaires. Each subject answered his/her drug alert related questions correctly. Subjects' perceptions about the various drug alert presentation interfaces are summarized in Table 3.

Interface to present multiple ADEs		ScrollText-View	Tree-View	TreeDashboard-View	Thermometer-View
Interface concept		most textual	less graphical more textual	less textual more graphical	most graphical
Cognitive style for drug alert presentation		text-reader			image-visualizer
Domain expert Assessment	Easy to catch critical information?	+	++	++++	+
	Easy to interpret?	++++	++++	++++	−
	Is interface compact?	−	++	++++	+
	Information sufficient to make order decision?	++	++	+++	−

Table 3: Comparison of prototype interfaces

Domain experts favored a drug alert presentation interface in which they could quickly locate critical information related to each drug alert. Display of critical alert attributes, ease of interpretation, sufficient patient-related and drug-related information, and fast navigation among various alerts were considered major factors by the domain experts evaluating the usability of the alert presentations during e-Rx practice. Domain experts believed that an interface that uses both

text and intuitive graphics metaphors better achieved the implementation goals.

Conclusion

We were able to map existing alert attributes to prototype user interfaces. Our review results suggested that domain experts preferred a presentation method that used both text and graphics to depict critical information related to each drug alert. The TreeDashboard-View appeared to be the preferred prototype interface in this study (Table 3).

We used this feedback in subsequent work, as described in the next chapter.

CHAPTER IV

SYSTEM IMPLEMENTATION AND FORMAL USABILITY TESTING

Introduction

We postulated that novel user interfaces may be needed to dramatically decrease the "attention cost" of presenting clinical drug alerts in an e-Rx system. We had been able to map existing drug alert attributes (Category of alert, Severity, Frequency, Strength of Evidence, Description, Monograph) to prototype user interfaces as described in Chapter III, Table 2. Our Expert Review results suggested that domain experts preferred a presentation method that uses both text and graphics to depict critical information related to each drug alert. The TreeDashboard-View display appeared to be most favored among the four prototype interfaces studied. We used this information to address the following two aims, which will be described below:

1. Develop a robust prototype of the preferred user interface from Aim 1 (described in Chapter III) and integrate it into an existing e-prescribing platform.
2. Compare prescriber performance using a standard text display with performance using this preferred user interface, with particular focus on clinical appropriateness of prescriber's prescribing response, response time, prescriber's preference on two interfaces.

Before the application implementation, we also added one more drug alert attribute (showed in Table 4) into our information mapping based upon the feedback we received from Expert Review study.

Attribute	Description
Clinical effect	Pharmacological mechanism of interaction or contraindication (retrieved from FDB drug information knowledgebase)

Table 4: Clinical effect

Prototype Development

We implemented our prototype drug alert application into an existing system, Starpanel, that includes an e-prescribing application called RxStar. StarPanel is an electronic health record application deployed throughout VUMC. It integrates patient data from multiple sources that include demographics, lab results, radiology/cardiology/pathology reports, physician notes, physician letters, discharge summaries, problem lists, medication log, patient indicators/alerts, inpatient/outpatient/ED census, and external test results. It is fully integrated with RxStar. This allows access to all of the electronic patient clinical information from one single screen. StarPanel also support various ways to record the patient's data, as well as workflow via message basket, work-lists, new results, draft-and-sign, whiteboards, indicator, and consulting service, etc. StarPanel brings detailed patient-related information, at the moment that clinicians treat the patient, record the data, and communicate other clinicians.

RxStar is a web-based outpatient prescription writer designed to create a safe and efficiently generated prescription. It contains features designed to improve patient safety, including drug-allergy and drug-dose checking. RxStar is used throughout VUMC, allowing approximately 2000 prescribers to generate over 60,000 prescriptions each month. Because RxStar has been well-adopted, it represented the best platform to test the additional functionality of the clinical alert prototype.

The alert prototype interface retrieved patient medication information from RxStar (via

StarPanel), as well as drug alert information from First DataBank® drug information knowledgebases augmented with additional knowledge for certain attributes (e.g. Strength of Evidence) to simulate an integrated prescribing and decision support process. RxStar integration allowed the application to turn alerts on or off based on known patient information, such as age, weight, medical conditions (diagnosis), and current or new medications. The drug alert information was delivered to clinicians in real-time. In addition, the survey collection process was implemented directly into the drug alert prototype to calculate time-to-decision and other variables in the prescribing workflow as close to the decision point as possible.

The prototype was implemented using Perl and Javascript. Specifically, we introduced TreeDashboard-View (showed in Figure 6, details are described in Chapter III) and an additional standard text-based TextScrolling-View (showed in Figure 7, details are described in Chapter III) as a control interface. Figure 8 shows the prescription writer and drug alert prototype.

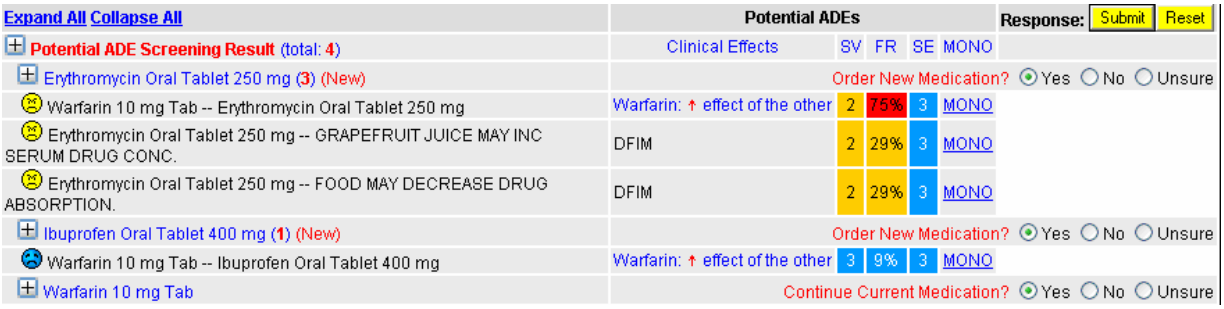


Figure 6: Drug alert information delivered by TreeDashboard-View

Figure 7: Drug alert information delivered by ScrollText-View

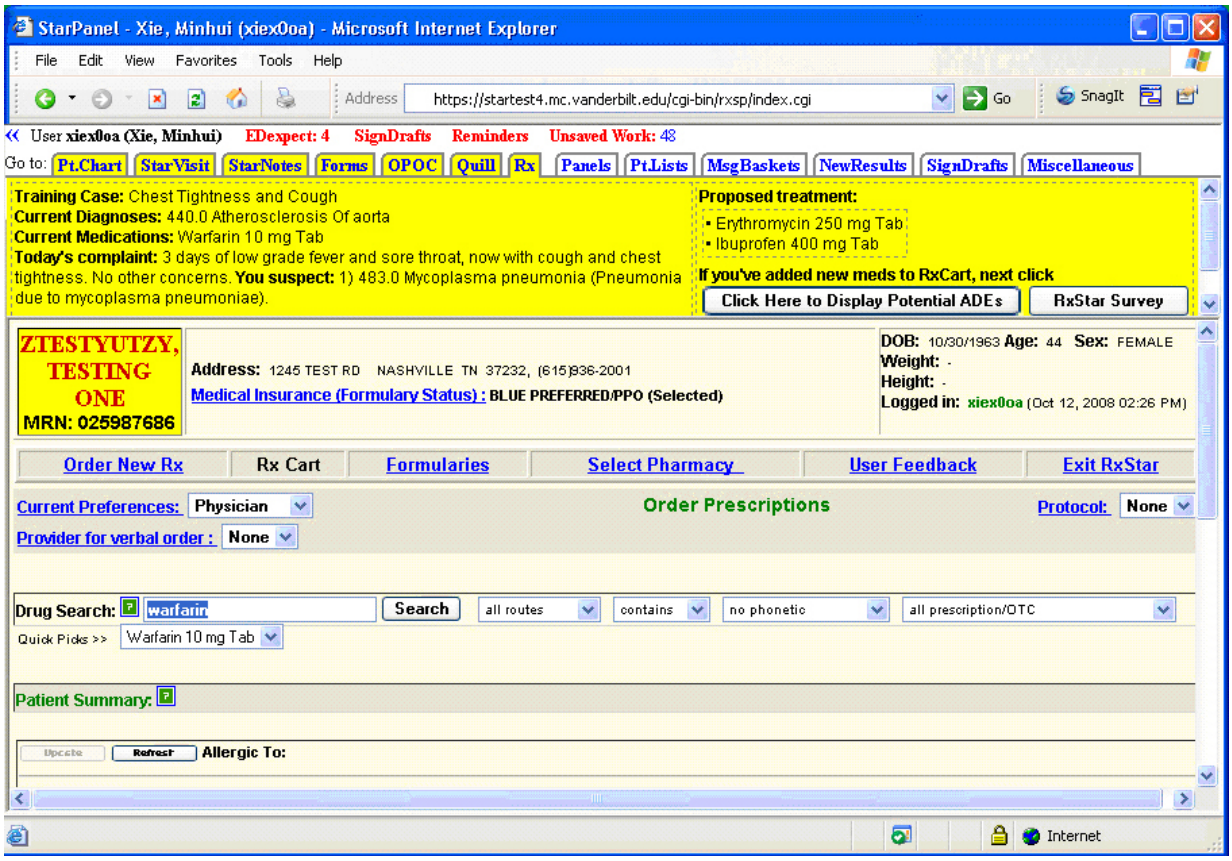


Figure 8: Prescription writer interface

We also designed an anonymous, computer-based, self-administered survey to measure the response time and attitudes of subjects toward different drug alert interfaces. The details of the enrollment form and questionnaire are shown in Appendix B and C.

Methods

Setting

Academic Medical Center

The Vanderbilt Clinic (TVC) is the outpatient facility of Vanderbilt University Medical

Center (VUMC). As of 2007, TVC had more than 900 Medical Group physicians on staff, comprising over 95 outpatient specialty practices in several locations and provides a full range of diagnostic and treatment services. In 2007, TVC had over one million outpatient visits.

Study Population

We recruited physician prescribers who were regular RxStar users from Internal Medicine/Meds-Peds (combined Internal Medicine and Pediatrics) and who did not participate in the Expert Review or Pilot Study phase of the project. The study's description and purpose were introduced to all target participants by the VUMC Chief Hospital Informatics Officer (also an Internal Medicine physician) via email. Physicians were provided with details about the project. The first 12 responders were invited to participate in the study. We used the other respondents as alternates if we could not schedule a session with any of the original respondent group.

Before the study was administered, pilot study and power analysis were conducted to estimate the sample size. The study design was approved by the Vanderbilt University Medical Center Institutional Review Board. After receiving all study information, agreement to participate was considered informed consent.

Study Environment

The study took place in a quiet cubicle to allow the participant to focus on the task of deciding whether or not to prescribe a medication, and so that we could simulate the types of distractions that predispose to errors in prescribing decisions. Figure 9 shows the study environment, including a Clinical Workstation (CWS) and audio instrument. During the study, the participant would hear prerecorded background noise simulating a primary adult care unit setting. The noise

included phone's ringing, page's beeping, and people talking and walking.

Figure 9: Simulation lab with CWS workstation and audio-taped distraction instruments

Study Materials

We conducted a formal usability test (28) using simulated patient cases to compare the effectiveness of the TreeDashboard-View versus the standard ScrollText-View. Our hypothesis was that the TreeDashboard-View would decrease the response time of the alerts, where the response time was defined as the time from the display of the alerts to the time the prescriber made a

decision to override or to cancel the prescription, all while distracted by random but typical clinic noise.

The two simulated patient cases included patient's demographics, diagnosis, current medications, new prescribed medication, available laboratory information, etc. The patient-related information was displayed on the same screen as the prescription writer. The simulated patient cases represented different but common adult primary care prescribing situations that were similar in complexity. The details of simulated patient cases used for training and in the study are provided in Appendix D.

A 10-page study packet included a cover page and a color instruction manual (Appendix E). The cover page explained the purpose of the survey study. The instruction manual provided detailed instructions to complete the study. An enrollment form was provided to each participant before the study and asked about the participants' current role, department/unit, years of RxStar use, and years of StarPanel use.

An exit survey was developed to rate both drug alert interfaces with regard to two themes: quality of care and efficiency. Quality of care questions addressed 4 constructs:

1. Usefulness of drug alerts
2. Ability to detect critical information
3. Ability to accomplish tasks
4. Is information sufficient to make a prescribing decision

Efficiency consisted of two constructs: (1) ability to use without additional training; and (2) ability to find necessary information when making a prescribing decision.

Participants' responses to the two drug alert interfaces were captured using a 10-point scale (1~10) as structured in the Questionnaire for User Interface Satisfaction survey (38), for example,

ranging from "1- Hard to detect critical information," to "10 – Easy to detect critical information", or from "1- Inefficient to accomplish tasks," to "10 – Efficient to accomplish tasks", etc. where appropriate. Participants were also provided with four free-text comment box questions to solicit their thoughts and comments with regard to either drug alert interface.

Finally, we graded each prescriber's response to the alert prototype based on a benchmark respfor each alert in each case provided by one senior physician (WCG) and verified by another domain expert (both are board-certificated internists). Grading used a 5-point (0~4) scale based on pre-defined rules (see Appendix C).

0 – No significant interaction or risk

1 – Slight or minimal risk for interactions

2 – Moderate risk for interactions (monitoring advisable)

3 – High risk for interactions (monitoring required and consider alternatives)

4 – Contraindication

Study Design

Figure 10 contains a graphical summary of the overall study design. Before beginning the study, each subject completed the enrollment data form, followed by a tutorial that described the interfaces and walked the study subject through a Starpanel, RxStar and drug alert prototype session, using a training case. Once this case was completed, the subject was automatically randomized to one of 4 possible series of screens, as shown below using a two-by-two counter-balanced presentation order scheme for case and drug alert interface.

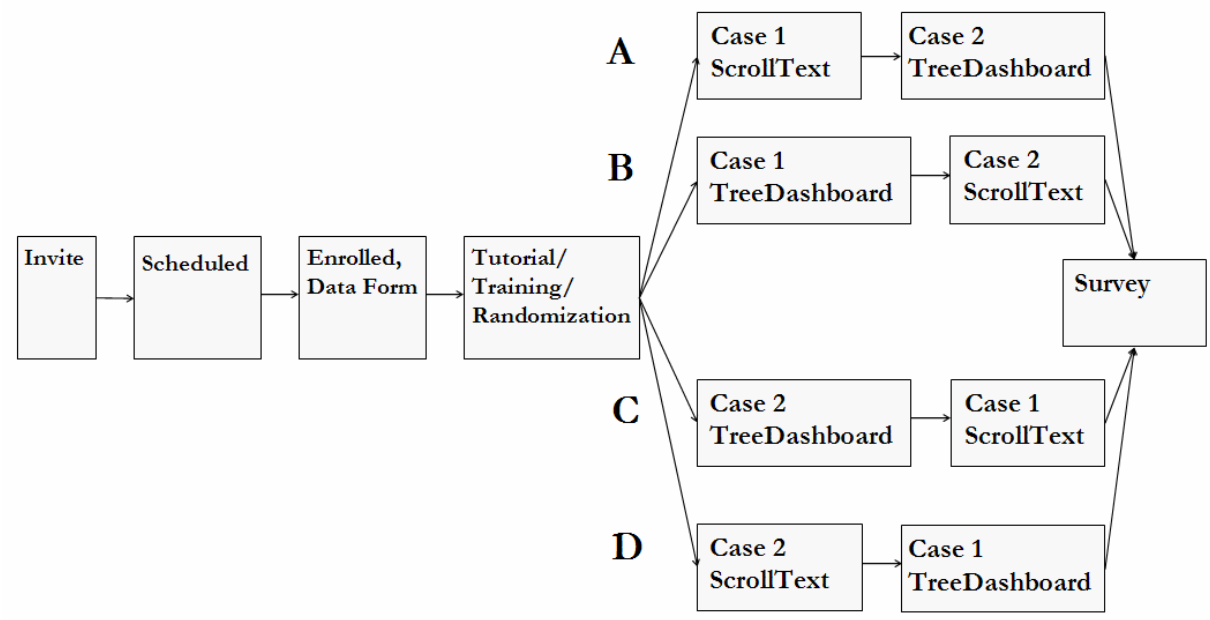


Figure 10: The flowchart of formal usability testing

Each study took about 40 minutes to complete. After a brief introduction (1 minute) there was a 15-minute training period. During the survey, participants used RxStar/StarPanel on a Clinic Workstation (CWS) desktop computer. The subject could only manipulate the keyboard and mouse. All participants followed the study instructions without any intervention from researchers.

The study was conducted over a four-week period (November 20, 2008 to December 15, 2008). All participants received a $15 Starbucks gift card or iPod earphone for appreciation upon study completion.

Data collection and analysis

The survey data were collected electronically. For each patient case that participant encountered, we recorded the response time as end time minus the start time where the start time is

when drug alert information is populated on the screen, and the end time is when the prescriber makes a final decision about prescribing medication by clicking the "submit decision" button. The participant was required to make a decision if prescribing or not for each drug including current medication and new mediation. The available decision options included "Yes", "No" or "Unsure".

The analysis used the response time per drug alert interface. We completed a Wilcoxon Paired Signed-Rank Test for a significant difference in the response time taken to make a prescription decision between the TreeDashboard-View and controlled ScrollText-View. The same analysis was applied to participants' overall perception toward the two drug alert interfaces. All statistical testing was performed using SPSS software, version 14.0 (SPSS). A difference was considered present if testing demonstrated a difference in the groups' means.

Survey sample size was derived from a pilot test of the interface using three board-certified physicians (two from Internal Medicine, one from Family Medicine practice with training and experiences in Biomedical Informatics).

In the pilot test, the response time using the ScrollText-View was 156 seconds, with a standard deviation of 35 seconds; and the mean response time for the TreeDashboard-View was 144 ± 39 seconds. The difference in response time between the two interfaces was 12 ± 5.6 seconds. Sample size was estimated using "Power and Sample Size Calculator" (version 2.1.20, released on February 2003) (39). A sample of 12 subjects would provide a power of 90% and an alpha level of 0.05 in the usability testing to determine a difference in the subjects' response time. Of note, the pilot used only domain experts, not regular physician prescribers, and presented all cases and drug alert interfaces in the same sequence (case 1 ScrollText-View; case 2 TreeDashboard-View).

Results

Subject enrollment

We emailed invitation letter to 135 potential participants right after the study was introduced via email to all target physicians by the hospital Chief Informatics Officer. 23 physicians signed up on-line and 12 physicians completed the study. Since we scheduled the respondent physicians to complete the study until we hit our target for 12 testers, the response rate was 17% (23 of 135). Of 12 physicians who completed the study, 11 were from Internal Medicine and one was from Med-Peds. Attending and resident physicians were equal in number. 75% of physicians (9 of 12) had more than 2 years experience of using RxStar/StarPanel. Table 5 summarizes the descriptive analysis results.

Department	Subjects	Percentage
Internal Medicine	11	91.7 %
Meds-Peds	1	8.3 %
Total	12	100 %

Role	Subjects	Percentage
Attending	6	50 %
Resident	6	50 %
Total	12	100 %

Yeas of Using RxStar	Subjects	Percentage
< 1	3	25 %
2	5	41.7 %
3	3	25 %
4+	1	8.3 %
Total	12	100 %

Yeas of Using StarPanel	Subjects	Percentage
< 1	2	16.7 %
2	3	25 %
3	3	25 %
4+	4	33.3 %
Total	12	100 %

Table 5: Descriptive analysis of enrollment distribution

Respo

We evaluated the overall response time between ScrollText-View and TreeDashboard-View.

The response time for the ScrollText-View was 122 ± 50 seconds, and for the TreeDashboard-View was 152 ± 61 seconds (p = .209, α = .05). Figure 11 shows the boxplot of response time of two drug alert interfaces

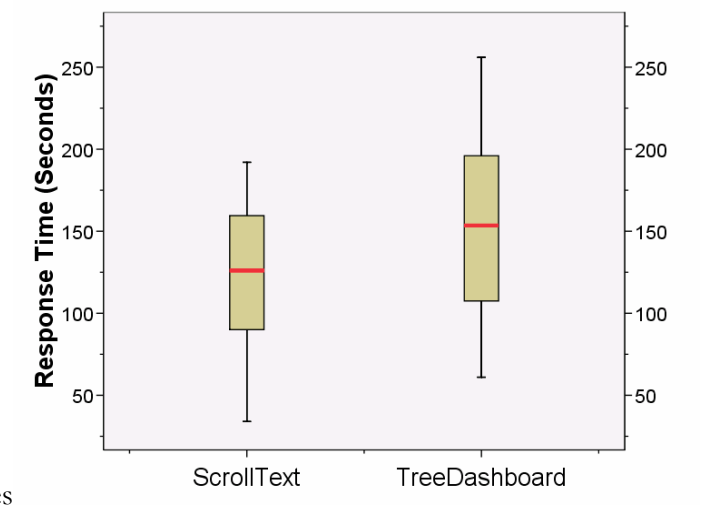


Figure 11: The response time of two drug alert interfaces

Clinical Appropriateness of Prescribers' responses

We also evaluated prescribers' responses with regard to the clinical appropriateness. Particularly, we graded each prescriber's response to the alert prototype based on a benchmark resp described in Method section. The result of the evaluation is summarized in Table 6. The result of correct response rate is summarized in Table 7.

	Number of prescribers' responses for each grade of clinical appropriateness				
	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
ScrollText-View	3	4	2	3	1
TreeDashboard-View	2	5	3	2	

* 5-point scale for clinical appropriateness was described earlier. Grade 4 is absolute contraindication.

Table 6: Clinical appropriateness of prescribers' responses

Drug Alert Interface	Correct Response Rate	
	Cut off by Grade 3	Cut off by Grade 4
ScrollText-View	66.7%	91.7%
TreeDashboard-View	83.3%	100%

Table 7: Correct response rate of prescribers' responses

One subject prescribed medications that were absolutely contraindicated according to drug alert information presented by the ScrollText-View. For the indicated patient case, Itraconazole should not be prescribed together with Simvastatin and Nexium due to the potential interactions between selected azole antifungal and HMG-COA reductase inhibitor (rhabdomyolysis, etc.), and between selected azole antifungal and proton pump inhibitor (Itraconazole's absorption is impaired by concurrent administration of Nexium). Other patient case encounters contained interactions of varying degrees. For instance, 3 subjects prescribed medications that contained grade 3 potential drug-drug interaction(s) presented by the ScrollText-View. 2 subjects prescribed medications that contained grade 3 potential drug-drug interaction(s) presented by the TreeDashboard-View.

Prescribers' perception analysis

We evaluated prescribers' perception on both drug alert interfaces (ScrollText-View and TreeDashboard-View). The results of the questionnaire are summarized in Table 8.

Questionnaire item	ScrollText-View		TreeDashboard-View		Paired Differences		p-value
	Mean score	SD	Mean score	SD	Mean	SD	
Quality of care item							
1. Usefulness of drug alerts	8.58	0.793	9.00	0.739	-0.417	0.669	.059
2. Ability to detect critical info.	6.33	1.826	9.08	0.793	-2.750	1.960	.005
3. Ability to accomplish tasks	6.67	1.497	8.25	0.754	-1.583	1.676	.001
4. Information sufficient to make a prescribing decision	8.67	.651	8.50	1.087	0.167	1.030	.705
Efficiency item							
1. Ease of use	6.42	1.929	7.58	1.505	-1.167	3.099	.234
2. Information easy to find	6.50	1.931	8.17	1.030	-1.667	2.103	.024

Table 8: The result of prescribers' perception

Four questionnaire items addressed proscribers' perception of quality of care. We considered that participants' perception was strongly positive if the rating score was ≥ 8 on the 10-point scale. When asked about the usefulness of drug alerts presented (question 1), the response was strongly positive with mean of 8.58 ± 0.793 for ScrollText-View, and 9.00 ± 0.739 for TreeDashboard-View, respectively. When asked if provided information is sufficient for the participant to make prescribing decision (question 6), the response was strongly positive with mean of 8.67 ± 0.653 for ScrollText-View, and mean of 8.50 ± 1.087 for TreeDashboard-View. When asked about how much the interface could help prescriber to accomplish prescribing task (question 4), the response was positive with mean of 6.67 ± 1.497 for ScrollText-View, and mean of 8.25 ± 0.754 for TreeDashboard-View. When asked about the ability to detect critical information (question

2), the response was surprisingly encouraging with a mean of 9.08 ± 0.793 for TreeDashboard-View.

Two questionnaire items addressed proscribers' perception of efficiency. When asked about the ease of use (question 3), the response was a mean of 6.42 ± 1.929 for ScrollText-View, and a mean of 7.58 ± 1.505 for TreeDashboard-View, respectively. When asked if provided information is easy to find for making prescribing decision (question 5), the mean response was 6.50 ± 1.931 for ScrollText-View, 8.17 ± 1.030 for TreeDashboard-View.

We performed Wilcoxon Paired Signed-Rank Test to determine if perception difference on questionnaire items existed between the two drug alert interfaces. The results are summarized in Table 8.

We also asked subjects to comment about different aspects of the interfaces. When asked "How enthusiastic would you be if VUMC implemented this interface within RxStar in your clinic", 11 of 12 subjects felt TreeDashboard-View was more enthusiastic, while one subject felt that it was moderate. Some subjects also asked for additional functionalities to be added into TreeDashboard-View for better performance. Table 10 showed the quotes from the comments we received.

Comment box questions	Quotes from comments
How enthusiastic would you be if VUMC implemented this interface (TreeDashboard-View) within RxStar in your clinic	• I would like this format I think this one would be easier to incorporate in daily workflow • This is a great interface and would be very helpful • Much more enthusiastic than the other interface • I would like this interface with some minor improvements
Describe what you like about this interface (TreeDashboard-View)	• Key information presented at a glance with color-coding and icons that are intuitive. Further information easily available with a click or two. • Color coding and separation of data into table-like format All actionable items are on the right of the screen • I love the color coding, the faces, the boxes of colors ... I am a visual learner and this set up is very useful for me • Clinical effects area (is good) could be expanded
Describe what you don't like about this interface (TreeDashboard-View)	• What exactly do the happy/sad faces reflect? • Maybe I don't remember that there are only 3 levels in your scale and that 2 is in the middle. What if that is 2 out of 6? • Smily/frowny faces are distracting and do not add more information • (I like) ability to review clinical data - switch windows would help • Option does not exist to alter dosages of already existing medication

Table 9: Quotes from prescribers' comments on TreeDashboard-View

Discussion

We designed and implemented a drug alert presentation application with clinical decision support using a commercial drug information knowledgebase. The alerting application was seamlessly integrated into an existing outpatient e-Rx system and used to simulate the prescribing process. The application contained a computer-based, self-administered survey to measure the

response time and attitudes of prescribers toward different drug alert interfaces aimed to deliver multiple drug alerts.

After an iterative design phase, we examined four different interfaces for presenting multiple drug alerts. Formal usability testing of the most promising interface (TreeDashboard-View) and controlled text-centric ScrollText-View demonstrated that physician prescribers agreed or strongly agreed that multiple drug alerts delivered by either were useful for e-Rx practice (both interfaces scored > 8.5 on a 10-point scale). Physcian prescribers agreed or strongly agreed that patient-related and drug alert information presented by both drug alert interfaces were adequate for them to make prescribing decision (both interfaces were scored ≥ 8.5 on a 10-point scale). Our evaluation of clinical appropriateness suggested that participants responded to both drug alert presentations acceptably. Only one subject prescribed medications that were absolutely contraindicated when presented by the ScrollText-View. Other prescribers' responses pertained to softer interactions of varying degrees that may or may not be clinically relevant therefore they are still considered as "appropriate".

Formal usability testing also demonstrated that physician prescribers had favorable impressions for drug alerts presented by the newly-designed TreeDashboard-View on quality of patient care and efficiency when compared to the controlled ScrollText-View. Out of the six questions asked for the TreeDashboard-View, five of six were favorable with a score > 8 on a 10 point scale (1~10). "Ease of use" had a mean score of 7.58 ± 1.505, which is still more favorable than the ScrollText-View. Wilcoxon Paired Signed-Rank Test revealed a statistically significant difference in participants' perception in the themes of quality of care and efficiency. Physician prescribers more likely agreed that the TreeDashboard-View is better than the ScrollText-View to detect critical alerts, to accomplish prescribing tasks, and to provide information helpful in making

ordering decisions ($p < 0.005$, 0.011, and 0.024, respectively).

The study also showed that physician prescribers' response time to the same set of drug alerts varied substantially, reflected by a high standard deviation. Although Wilcoxon Paired Signed-Rank Test failed to reveal statistically significant difference in the response time between the ScrollText-View and the TreeDashboard-View ($p = .209$, $\alpha = .05$), physician prescribers participating in the formal usability testing seemed to spend more time with multiple drug alerts presented by the TreeDashboard-View (152 ± 61 versus 122 ± 50 seconds of ScrollText-View). This is contrary to our expectations. We initially hypothesized that the novel TreeDashboard-View could help physician prescribers reduce their response time when evaluating multiple drug alerts. We can speculate an explanation based on comments collected from survey questionnaire. Traditionally, most drug alerts are delivered in text format using popup windows. Physician prescribers may be more familiar with the text-centric ScrollText-View. In contrast, there may be a learning curve to use the more novel TreeDashboard-View interface. This was indicated by prescribers' comments on negative aspects of the interface. Some precribers were confused about the scaling system (coloring schema and numbering schema) used in the TreeDashboard-View while an extra click was often required to obtain more detailed drug alert information. In this study, both simulated patient cases contained 6 drug-drug interaction and drug-food interaction alerts. The text-centric ScrollText-View may be still sufficient to handle this limited number of multiple drug alerts. In addition, some physicians noted that the TreeDashboard-View encouraged physicians to seek more information, thus slowing down but potentially providing better quality care during prescribing. An improvement in our scaling system and more tutorial/training time may help to reduce the prescribers' response time to TreeDashboard-View in the future study.

This study has many limitations that merit discussion. First, the ScrollText-View and the

TreeDashboard-View were implemented in a simple manner without the extensive user interface refinements of a commercial interface. Next, physician prescribers may need more time to adopt the multiple drug alerts delivered by the newly-designed TreeDashboard-View. Third, this study only investigated a single in-house developed e-Rx system with one commercial drug information knowledgebase support at one academic medical center. Physician participants were made up of housestaff in Internal Medicine and Med-Peds who were familiar with the in-house developed EHR/e-Rx applications in general. It is possible that effects with other systems at other institutes may differ from those reported here.

Of note, relative small sample size (12 physician prescribers in the formal usability testing) may limit statistical analysis in this study. We used convenience sampling (attendings and residents) and simulated patient cases that were limited to internal medicine and primary adult care setting, thus limiting generalization of the findings to community practitioners or specialists. In the next round of user interface testing, we may need to expand the design with a larger number of test subjects to allow for learning, and a greater variety of simulated patient cases selected for each target subspecialty likely to use this system. After this round of testing is completed, we may also want to expand the testing to include nurse practitioners as well.

Studies have previously demonstrated that e-Rx success depends upon several factors, including clinicians' access to e-Rx systems that is integrated into a single information workflow (1, 9, 20). In this study, we developed and compared prescribers' performance using different drug alert presentation methods in an existing e-Rx platform, with particular focus on clinical appropriateness of prescribing, the response time, and the prescribers' preferences. The relative small sample size (12 physician prescribers), while limiting for statistical purposes, still provides a basis for questions regarding the worthiness of the proposed novel drug alert TreeDashboard-View.

Conclusion

This study described issues in presenting multiple drug alerts in an outpatient e-Rx application integrated into EHR system. A robust model for studying multiple drug alert presentation was developed. Several novel drug alert presentation interfaces were introduced. Both expert evaluation and usability testing demonstrated that the TreeDashboard-View is viewed more favorably than the text-only view. Additional studies should be done on a refined version of this interface to improve its impact on accurate decision making and response time.

FUTURE WORK

This study will guide future work on the usability of multiple drug alert presentation interfaces in an existing outpatient e-Rx system. After the deployment of a preferred drug alert presentation interface, we hope to iteratively refine the interface design and evaluation of actual prescribing practices.

We collected feedback throughout the Expert Review and formal usability survey evaluations. After changes are made to the preferred drug alert presentation interface, the testing cycle could begin again, e.g., with a new domain expert panel, same or different group of physicians and nurses, to assess the effects of the changes. This type of usability testing (Expert Review and formal usability survey) can be conducted repeatedly throughout the software life cycle of e-Rx system. The prototypes of the drug alert presentation and self-administrated survey interfaces developed in this study will provide benchmarks against which improvement can be measured in different testing scenarios.

The outpatient e-Rx system and EHR system used for this study already supports clinical decision supports including Drug Allergy Conflicts, Dose Range Checking, Drug-Drug interaction, Drug-Food Interaction, Duplicate Ingredient, Geriatric Precautions, and Lactation Precautions (provided by commercial FDB drug information knowledgebases). The results of our findings will be presented to the e-Rx development team. After the design of a preferred drug alert presentation interface is finalized, our hope is its integration would be seamless and cost-effective.

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APPENDIX A: STORYBOARD

Cover Letter

This is a pilot survey to evaluate **new ways** to visualize alerts and reminders in an e-prescribing system. It consists of a series of user interfaces (UI) for displaying adverse drug event (ADE) alerts. Please read the instructions for each type of display before reviewing the screen images and filling out the questionnaire.

Thank you for participating!

1

Introduction

Key terms and abbreviations (ignore others):

ADE – adverse drug event; any unexpected or dangerous reaction to a drug

DDCM – drug-disease contraindications

DDIM – drug-drug interaction

DAM – drug-allergy interaction

SV – severity of the interaction or contraindication (retrieved from a drug knowledge database)

Scales:	3	→	2	→	1
Representation:	minimum	→	moderate	→	Critical

FR – frequency (this information is retrieved from mock-up database at real-time)

Scales:	0%	→	10%	→	30%
Representation:	minimum	→	moderate	→	Critical

SE – strength of evidence supporting the warning (FAKE DATA – shown for demonstration purposes only)

Scales:	3	→	2	→	1
Representation:	minimum	→	moderate	→	Critical

TX – detailed text description of alert (retrieved from FirstDataBank drug knowledge database)

MONO – monograph, which includes information on drug's pricing, adverse reactions, contraindications, pharmacokinetics as well as related drug monograph topics (retrieved from FirstDataBank drug knowledge database if there exists)

2

Description of User Interface:

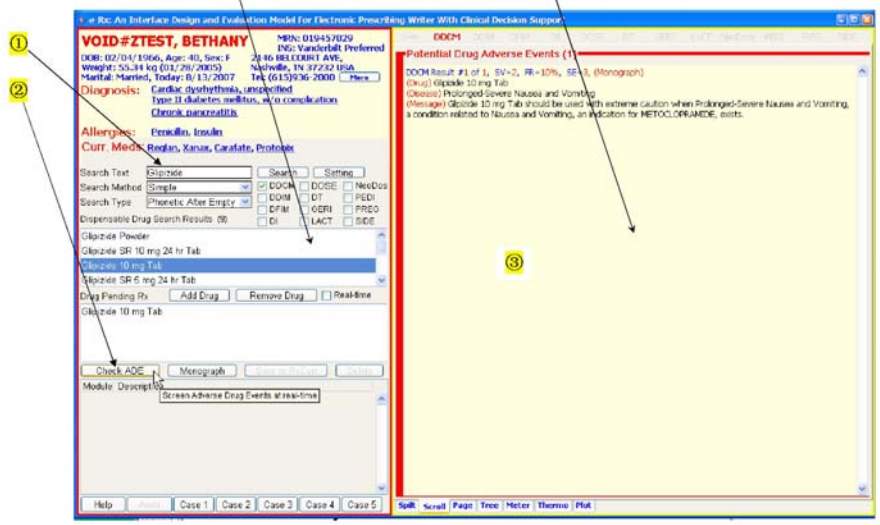
The user interface of e-prescribing system is divided into **two parts**:
a Rx writer on the **left**, and a clinic alert collector on the **right**.

Clinician can:

① **Input/select** different patient and drug profiles (demographics, diagnosis, allergies, current medications);

② **Click** "Check ADE" button.

③ The potential ADE alert information is displayed in the different formats on the right side of screen.

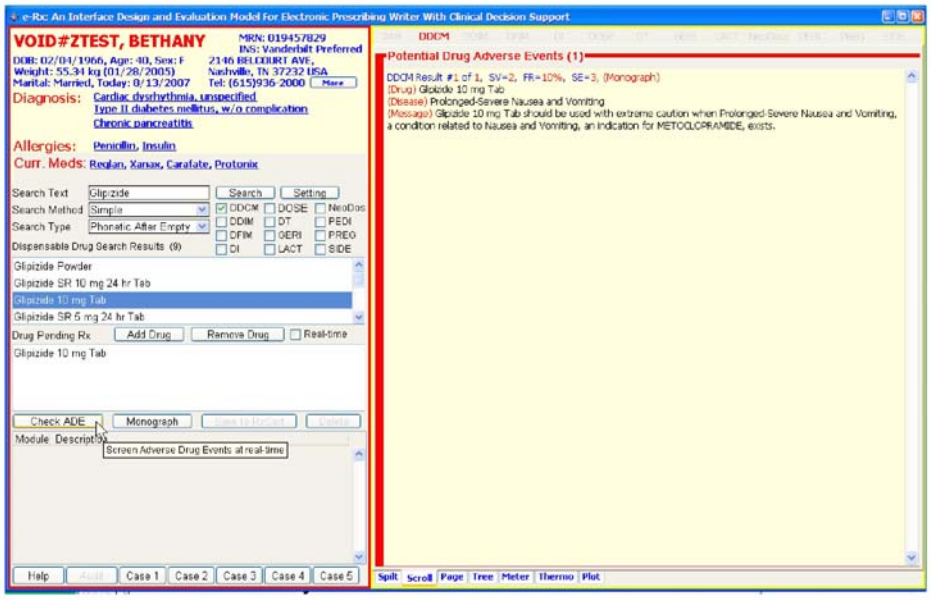


3

Novel Presentation Model For Drug Alerting – Warm-up Exercise **ID: 100-01**

Instruction:

The patient is already taking the medications of Reglan (Metoclopramide), Xanax, Carafate, and Protonix. On the screen, you have typed 'Glipizide', selects proper routes and doses, and pressed the 'Check ADE' button; you now see the ADE alerts displayed on the right. Please focus on the alert section and answer the following 6 questions on the next page:



4

Novel Presentation Model For Drug Alerting – Warm-up Exercise **ID: 100-02**

Question #1

What important attributes about an alert are presented on this screen? Circle the precise answers below:

1) Severity
2) Frequency/Likelihood of occurrence
3) Strength of evidence
4) Text Description
5) Monograph

How clearly is this alert displaying information? Please explain:

Question #2

What does this display mean? Circle all that apply.

1) The system is reporting a large number of ADEs (Adverse Drug Alerts)
2) This screen will let you read information of potential ADEs
3) There are several DAM ADEs.
4) There are several DFIM ADEs.

Alternatively, you can describe what is happening here:

Question #3

What have you observed? Circle the precise answers below:

1) The medication has not generated a Lactation warning
2) The patient is receiving an overdose of Glipizide
3) Glipizide could have an ADE (Adverse Drug Event) risk in this patient
4) There is an interaction between Glipizide and Caffeine

Alternatively, you can describe what is happening here:

Question #4

Is the information on the interface sufficient to help you decide whether or not to order this set of medications? Please explain.

Question #5

Describe what you like about this interface:

Question #6

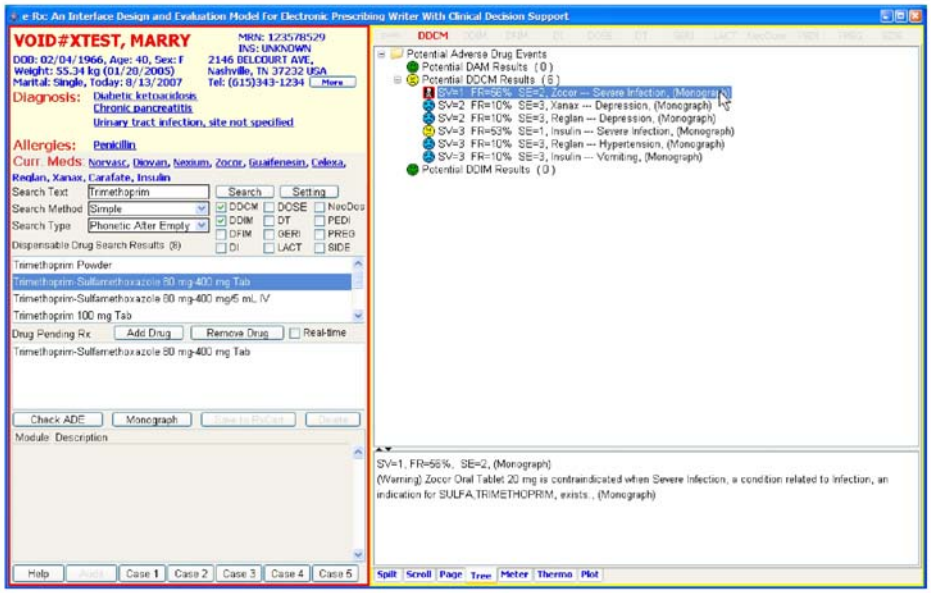
Describe one thing you don't like:

5

Novel Presentation Model For Drug Alerting – Model #1 **ID: 101-01**

Instruction:

The patient is already taking the medications of Zocor, Xanax, Reglan, Insulin, etc. On the screen, you have typed 'Trimethoprim', selects proper routes and doses, and pressed the 'Check ADE' button; you now see the ADE alerts displayed on the right. Please focus on the alert section and answer the following 6 questions on the next page:



6

Novel Presentation Model For Drug Alerting – Model #1 **ID: 101-02**

Question #1
What important attributes about an alert are presented on this screen? Circle the precise answers below:

1) Severity
2) Frequency/Likelihood of occurrence
3) Strength of evidence
4) Text Description
5) Monograph

How clearly is this alert displaying information? Please explain:

Question #2
What does this display mean? Circle all that apply.

1) The system is reporting a large number of ADEs (Adverse Drug Alerts)
2) This screen will let you read information of potential ADEs
3) There are several DAM ADEs
4) There are several DFIM ADEs

Alternatively, you can describe what is happening here:

Question #3
What have you observed? Circle the precise answers below:

1) The medication has not generated a Lactation warning
2) The patient is receiving an overdose of Norvasc
3) Zocor could have an ADE (Adverse Drug Event) risk in this patient
4) There is an interaction between Zocor and Caffeine

Alternatively, you can describe what is happening here:

Question #4
Is the information on the interface sufficient to help you decide whether or not to order this set of medications? Please explain.

Question #5
Describe what you like about this interface:

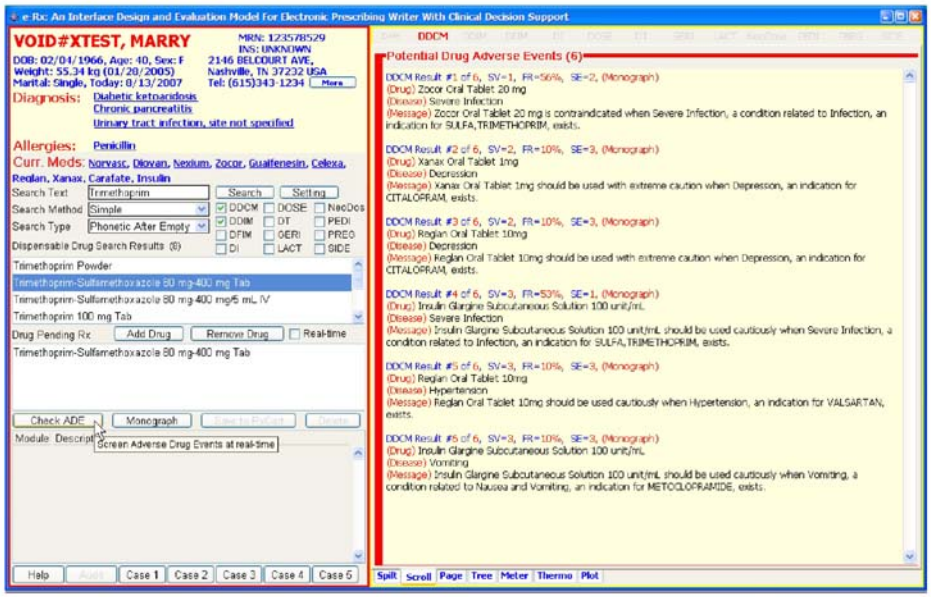
Question #6
Describe one thing you don't like:

7

Novel Presentation Model For Drug Alerting – Model #2 **ID: 102-01**

Instruction:

The patient is already taking the medications of Zocor, Xanax, Reglan, Insulin, etc. On the screen, you have typed 'Trimethoprim', selects proper routes and doses, and pressed the 'Check ADE' button; you now see the ADE alerts displayed on the right. Please focus on the alert section and answer the following 6 questions on the next page:



8

Novel Presentation Model For Drug Alerting – Model #2 **ID: 102-02**

Question #1
What important attributes about an alert are presented on this screen? Circle the precise answers below:

1) Severity
2) Frequency/Likelihood of occurrence
3) Strength of evidence
4) Text Description
5) Monograph

How clearly is this alert displaying information? Please explain:

Question #2
What does this display mean? Circle all that apply.

1) The system is reporting a large number of ADEs (Adverse Drug Alerts)
2) This screen will let you read information of potential ADEs
3) There are several DAM ADEs
4) There are several DFIM ADEs

Alternatively, you can describe what is happening here:

Question #3
What have you observed? Circle the precise answers below:

1) The medication has not generated a Lactation warning
2) The patient is receiving an overdose of Norvasc
3) Zocor could have an ADE (Adverse Drug Event) risk in this patient
4) There is an interaction between Zocor and Caffeine

Alternatively, you can describe what is happening here:

Question #4
Is the information on the interface sufficient to help you decide whether or not to order this set of medications? Please explain.

Question #5
Describe what you like about this interface:

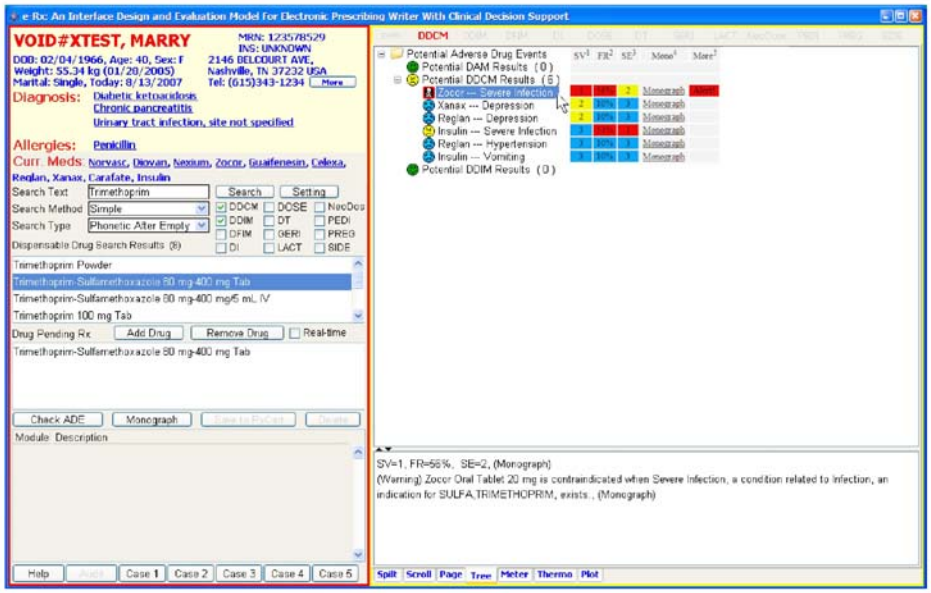
Question #6
Describe one thing you don't like:

9

Novel Presentation Model For Drug Alerting – Model #3 **ID: 103-01**

Instruction:

The patient is already taking the medications of Zocor, Xanax, Reglan, Insulin, etc. On the screen, you have typed 'Trimethoprim', selects proper routes and doses, and pressed the 'Check ADE' button; you now see the ADE alerts displayed on the right. Please focus on the alert section and answer the following 6 questions on the next page:



10

Novel Presentation Model For Drug Alerting – Model #3 **ID: 103-02**

Question #1
What important attributes about an alert are presented on this screen? Circle the precise answers below:

1) Severity
2) Frequency/Likelihood of occurrence
3) Strength of evidence
4) Text Description
5) Monograph

How clearly is this alert displaying information? Please explain:

Question #2
What does this display mean? Circle all that apply.

1) The system is reporting a large number of ADEs (Adverse Drug Alerts)
2) This screen will let you read information of potential ADEs
3) There are several DAM ADEs
4) There are several DFIM ADEs

Alternatively, you can describe what is happening here:

Question #3
What have you observed? Circle the precise answers below:

1) The medication has not generated a Lactation warning
2) The patient is receiving an overdose of Norvasc
3) Zocor could have an ADE (Adverse Drug Event) risk in this patient
4) There is an interaction between Zocor and Caffeine

Alternatively, you can describe what is happening here:

Question #4
Is the information on the interface sufficient to help you decide whether or not to order this set of medications? Please explain.

Question #5
Describe what you like about this interface:

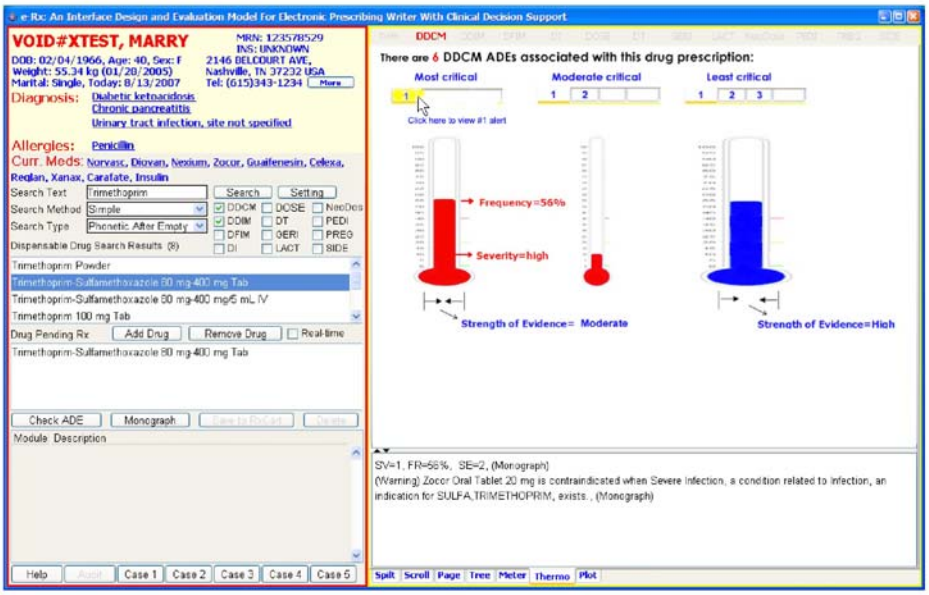
Question #6
Describe one thing you don't like:

11

Novel Presentation Model For Drug Alerting – Model #4 **ID: 104-01**

Instruction:

The patient is already taking the medications of Zocor, Xanax, Reglan, Insulin, etc. On the screen, you have typed 'Trimethoprim', selects proper routes and doses, and pressed the 'Check ADE' button; you now see the ADE alerts displayed on the right. Please focus on the alert section and answer the following 6 questions on the next page:



12

Novel Presentation Model For Drug Alerting – Model #4 **ID: 104-02**

Question #1
What important attributes about an alert are presented on this screen? Circle the precise answers below:

1) Severity
2) Frequency/Likelihood of occurrence
3) Strength of evidence
4) Text Description
5) Monograph

How clearly is this alert displaying information? Please explain:

Question #2
What does this display mean? Circle all that apply.

1) The system is reporting a large number of ADEs (Adverse Drug Alerts)
2) This screen will let you read information of potential ADEs
3) There are several DAM ADEs
4) There are several DFIM ADEs

Alternatively, you can describe what is happening here:

Question #3
What have you observed? Circle the precise answers below:

1) The medication has not generated a Lactation warning
2) The patient is receiving an overdose of Norvasc
3) Zocor could have an ADE (Adverse Drug Event) risk in this patient
4) There is an interaction between Zocor and Caffeine

Alternatively, you can describe what is happening here:

Question #4
Is the information on the interface sufficient to help you decide whether or not to order this set of medications? Please explain.

Question #5
Describe what you like about this interface:

Question #6
Describe one thing you don't like:

13

Thank you for completing the survey !

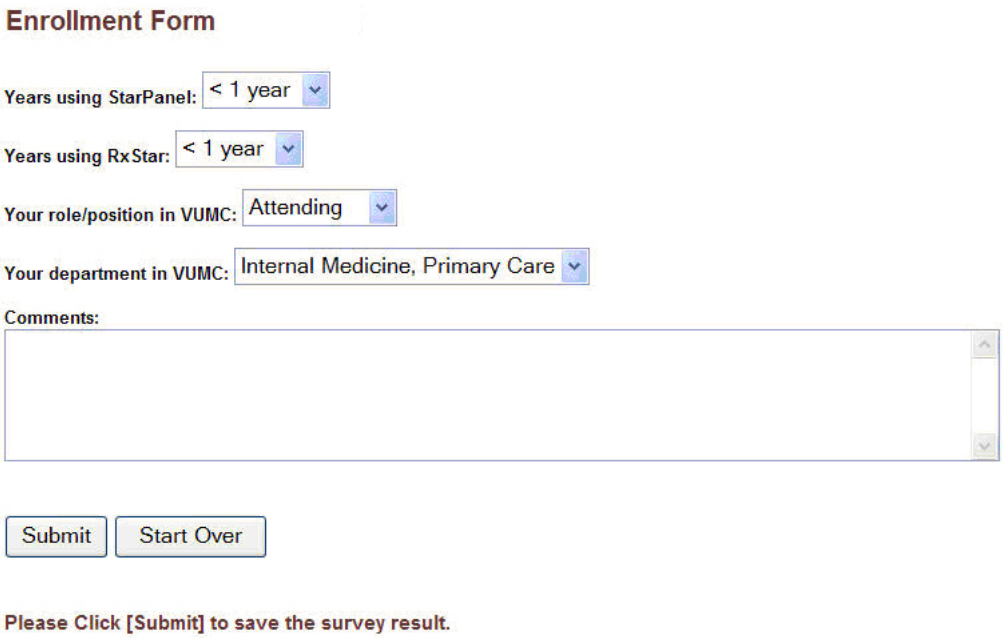
Please get my attention when you return the survey back to Charlie.
It's indeed my pleasure to work with you on the project !

Minhui (Charlie) Xie
Dept. of Biomedical Informatics
Vanderbilt University

Tel: (615) 936-5037
E-Mail: charlie.xie@vanderbilt.edu

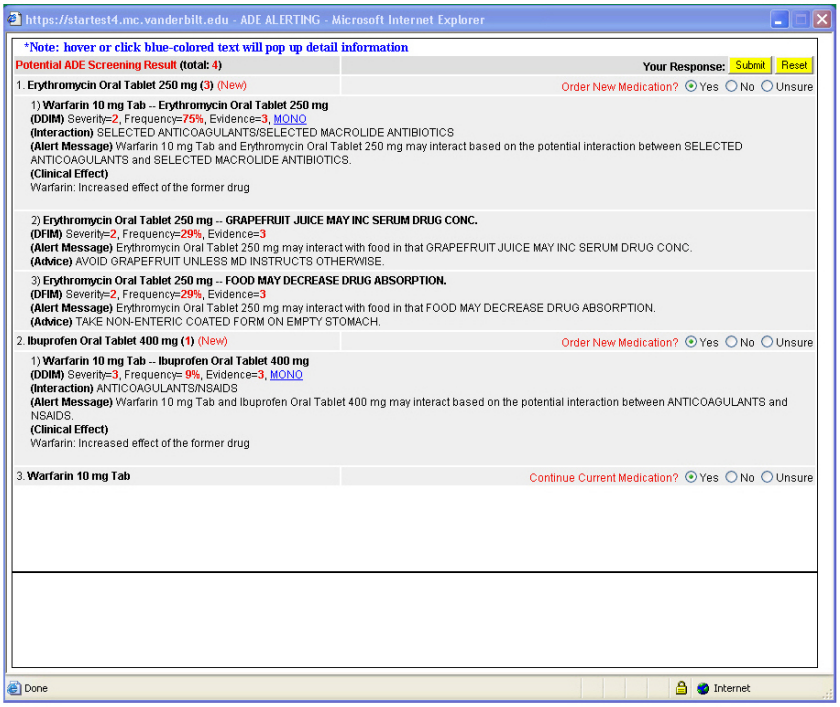
14

APPENDIX B: ENROLLMENT FORM



APPENDIX C: QUESTIONNAIRE

PART 1: **For the Presentation of Drug Alerts:**



Please choose appropriate scale for each question:

	SCREEN DESIGN AND LAYOUT		0	1	2	3	4	5	6	7	8	9		NA
1	Usefulness of drug alerts	useless	○	○	○	○	○	○	○	○	○	○	useful	○
2	Ability to detect critical information	hard	○	○	○	○	○	○	○	○	○	○	easy	○
3	Ease of use	impossible to understand	○	○	○	○	○	○	○	○	○	○	intuitive	○
4	Ability to accomplish tasks	inefficient	○	○	○	○	○	○	○	○	○	○	efficient	○
5	Is information easy for you to find when making ordering decision	hard	○	○	○	○	○	○	○	○	○	○	easy	○
6	Is information enough for you to make ordering decision	insufficient	○	○	○	○	○	○	○	○	○	○	sufficient	○

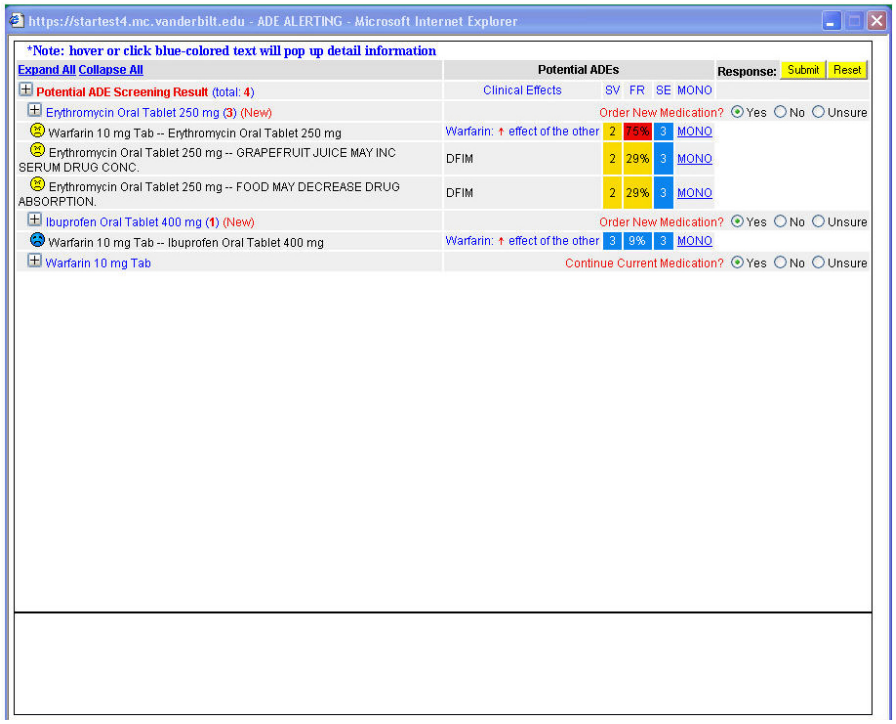
7. How is the information on the interface insufficient to help you decide whether or not to order this set of medications?

8. Describe what you like about this interface:

9. Describe specific ways in which this interface could be improved.

10. How enthusiastic would you be if VUMC implemented this interface within RxStar in your clinic?

PART 2: For the Presentation of Drug Alerts:



SCREEN DESIGN AND LAYOUT			0	1	2	3	4	5	6	7	8	9		NA
1	Usefulness of drug alerts	useless	○	○	○	○	○	○	○	○	○	○	useful	○
2	Ability to detect critical information	hard	○	○	○	○	○	○	○	○	○	○	easy	○
3	Ease of use	impossible to understand	○	○	○	○	○	○	○	○	○	○	intuitive	○
4	Ability to accomplish tasks	inefficient	○	○	○	○	○	○	○	○	○	○	efficient	○
5	Is information easy for you to find when making ordering decision	hard	○	○	○	○	○	○	○	○	○	○	easy	○
6	Is information enough for you to make ordering decision	insufficient	○	○	○	○	○	○	○	○	○	○	sufficient	○

7. How is the information on the interface insufficient to help you decide whether or not to order this set of medications?

8. Describe what you like about this interface:

9. Describe specific ways in which this interface could be improved.

10. How enthusiastic would you be if VUMC implemented this interface within RxStar in your clinic?

APPENDIX D: SIMULATED PATIENT CASES

Training Case MR# 015655871 and MR# 025987686 - Chest Tightness and Cough

- **Current Diagnoses:**
  440.0 Atherosclerosis Of aorta

- **Current Medications**
  Warfarin 10 mg Tab

- **Today's complaint**
  3 days of low grade fever and sore throat, now with cough and chest tightness. No other concerns. You suspect 1) 483.0 Mycoplasma pneumonia (Pneumonia due to mycoplasma pneumoniae).

- **Proposed treatment**
  Erythromycin 250 mg Tab
  Ibuprofen 400 mg Tab

- **Case Alerts**

Potential Drug-Drug Interaction

Warfarin 10 mg Tab and Erythromycin Oral Tablet 250 mg may interact based on the potential interaction between SELECTED ANTICOAGULANTS and SELECTED MACROLIDE ANTIBIOTICS.

Warfarin 10 mg Tab and Ibuprofen 400 mg Tab may interact based on the potential interaction between ANTICOAGULANTS and NSAIDS.

Erythromycin Oral Tablet 250 mg may interact with food in that FOOD MAY DECREASE DRUG ABSORPTION.

Erythromycin Oral Tablet 250 mg may interact with food in that GRAPEFRUIT JUICE MAY INC SERUM DRUG CONC.

Response

N/A

Formal Survey Case MR# 025987702 - Trouble swallowing and frequent heartburn

- **Current Diagnoses:**
  272.0 Hypercholesterolemia, pure
  309.28 Adjustment disorder with mixed anxiety and depressed mood
  401.1 Benign essential hypertension

- **Current Medications**
  Simvastatin Oral Tablet 20 mg (Zocor)
  Diovan HCT 160 mg-12.5 mg Tab
  Alprazolam Oral Tablet 1 mg (Xanax)

- **Today's complaint:**
  2 days of trouble swallowing and frequent heartburn in the lower part of the mid-chest and behind the breast bone; other concerns include 2 months of thickening of the nails on the left foot and decrease in appetite and insomnia nearly every day for two weeks. You suspect: 1) 530.81 Esophageal reflux; 2) 110.1 Onychomycosis.

- **Proposed treatment**
  Nexium Oral Capsule, Delayed Release(E.C.) 40 mg
  Itraconazole Oral Capsule 100 mg
  Fluoxetine Oral Capsule 20 mg
  Zolpidem 10 mg Tab

- **Case Alerts and Action**

Potential Drug-Drug Interaction

Itraconazole Oral Capsule 100 mg and Simvastatin Oral Tablet 20 mg (Zocor) may interact based on the potential interaction between SELECTED AZOLES and SELECTED HMG-COA REDUCTASE INHIBITORS.

Itraconazole Oral Capsule 100 mg and Alprazolam Oral Tablet 1 mg (Xanax) may interact based on the potential interaction between SELECTED AZOLE ANTIFUNGAL and SELECTED BENZODIAZEPINES.

Itraconazole Oral Capsule 100 mg and Nexium Oral Capsule, Delayed Release(E.C.) 40 mg may interact based on the potential interaction between SELECTED AZOLE ANTIFUNGALS and PROTON PUMP INHIBITORS.

Alprazolam Oral Tablet 1 mg (Xanax) and Fluoxetine Oral Capsule 20 mg may interact based on the potential interaction between BENZODIAZEPINES and SSRI'S; NEFAZODONE.

Itraconazole Oral Capsule 100 mg may interact with food in that FOOD INCREASES ABSORPTION OF CAPSULES.

Response

Order Yes:
Nexium Oral Capsule, Delayed Release(E.C.) 40 mg
Zolpidem 10 mg Tab
Fluoxetine Oral Capsule 20 mg

Order No or Unsure: (agree with alert content; or need more info.; or will find an alternative medication, etc.)
Itraconazole Oral Capsule 100 mg

Formal Survey Case MR# 025987728 - Worsening shortness of breath and cough

- **Current Diagnoses:**
  427.9 Cardiac dysrhythmia, unspecified
  493.2 Chronic Obstructive Asthma
  401.1 Benign essential hypertension

- **Current Medications**
  Diltiazem HCl Oral Capsule, Sust. Release 24 hr 240 mg (Cartia XT)
  Diovan HCT Oral Tablet 160-12.5 mg
  Advair Diskus 250 mcg-50 mcg/Dose for Inhalation

- **Today's complaint:**
  One week of worsening shortness of breath and cough. Unable to tolerate walking exercise that the patient has been able to do in the past. Other concerns include decrease in appetite and insomnia nearly every day for one week. You suspect: 1) 428.0 Congestive heart failure, unspecified; 2) 402.01 Hypertensive heart disease with heart failure; 3) 780.52 Insomnia, unspecified.

- **Proposed treatment**
  Digoxin Oral Tablet 125 mcg
  Enalapril Maleate 10 mg Tab
  Spironolactone Oral Tablet 50 mg (Aldactone)
  Zolpidem 10 mg Tab

- **Case Alerts and Action**

Potential Drug-Drug Interaction

Digoxin Oral Tablet 125 mcg and Diltiazem HCl Oral Capsule, Sust. Release 24 hr 240 mg may interact based on the potential interaction between DIGOXIN and CALCIUM CHANNEL BLOCKERS.

Digoxin Oral Tablet 125 mcg and Diovan HCT 160 mg-12.5 mg Tab may interact based on the potential interaction between DIGITALIS GLYCOSIDES and KALURETICS.

Digoxin Oral Tablet 125 mcg and Spironolactone 50 mg Tab may interact based on the potential interaction between DIGOXIN and SPIRONOLACTONE.

Enalapril Maleate 10 mg Tab and Spironolactone 50 mg Tab may interact based on the potential interaction between ACE INHIBITORS; ARB'S and POTASSIUM SPARING DIURETICS.

Diovan HCT 160 mg-12.5 mg Tab and Spironolactone 50 mg Tab may interact based on the potential interaction between ACE INHIBITORS; ARB'S and POTASSIUM SPARING DIURETICS.

Response

Order Yes:
Digoxin Oral Tablet 125 mcg
Enalapril Maleate 10 mg Tab
Provigil 100mg tab

Order No or Unsure: (agree with alert content; or need more info.; or will find an alternative medication, etc.)
Spironolactone 50 mg Tab

APPENDIX E: STUDY PACK

Cover Letter

Thank you for agreeing to participate in this study. Our goal is to improve the way alerts and reminders are displayed in electronic prescription systems such as **RxStar**. We have created two versions of a display -- your job is to use both and to provide us with feedback.

The study is taking place in this simulation room so that we can allow you to focus on the task of deciding whether or not to prescribe a medication, and so that we can simulate the types of distractions that often lead to errors in decision making. During this study, you will hear some noises that you should do your best to ignore. You are being timed, but accuracy counts!

Key terms and abbreviations (ignore others):

ADE – adverse drug event; any unexpected or dangerous reaction to a drug

DDIM – drug-drug interaction

DFIM – drug-food interaction

SV – severity of the interaction or contraindication (retrieved from a drug knowledge database)

Scales:	3	→	2	→	1
Representation:	minimum	→	moderate	→	Critical

FR – frequency (prevalence of the interaction, FAKE DATA – shown for demonstration purposes only)

Scales:	0%	→	10%	→	30%
Representation:	Minimum	→	moderate	→	Critical

SE – strength of evidence supporting the warning (FAKE DATA – shown for demonstration purposes only)

Scales:	3	→	2	→	1
Representation:	minimum	→	moderate	→	Critical

MONO – monograph, which includes information on drug's pricing, adverse reactions, contraindications, pharmacokinetics as well as related drug monograph topics (retrieved from FirstDataBank drug knowledge database if there exists)

The next **4** pages of this packet will take you through two training cases so that you can become familiar with the process and have any questions answered. Please turn the packet/page to begin.

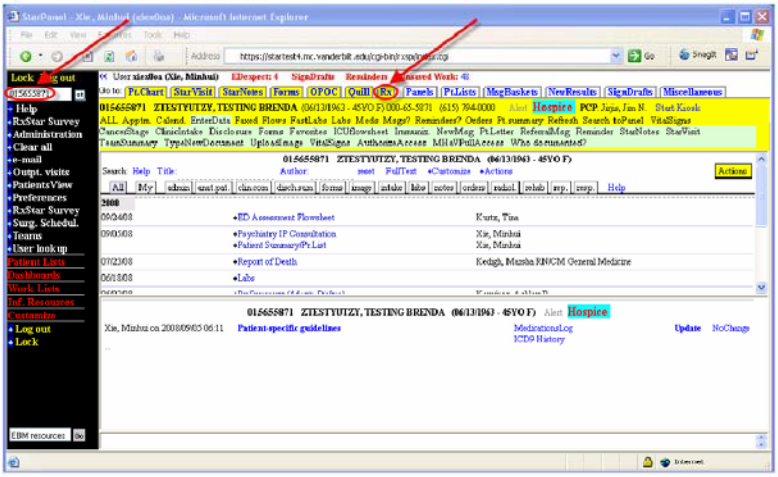
1

1st Training Case – Instruction Sheet for MR# 015655871

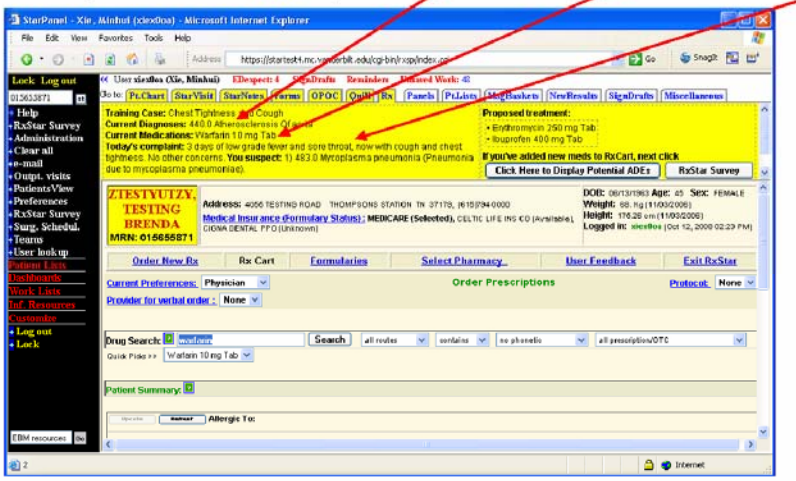
1) The computer in front of you should have the logon page to StarPanel. If not, open Internet Explorer, go to the website: **https://startest6.mc.vanderbilt.edu/cgi-bin/rxsp/**
Login using your username and password;

2) Pull up the patient chart **MR# 015655871** named **"Ztestyutzy, Testing Brenda"**;

3) **Now, click the Rx tab to start RxStar;**



4) Review this patient's profile including **"Current Diagnosis"**, **"Current Medications"**, **"Today's Complaint"** under the Rx tab;



5) Using RxStar, search for Erythromycin, Ibuprofen respectively; and add the prescriptions for:
Erythromycin 250 mg Tab, tid, 14 days
Ibuprofen 400 mg Tab, bid, 14 days

Once they are in the cart, turn to the next page

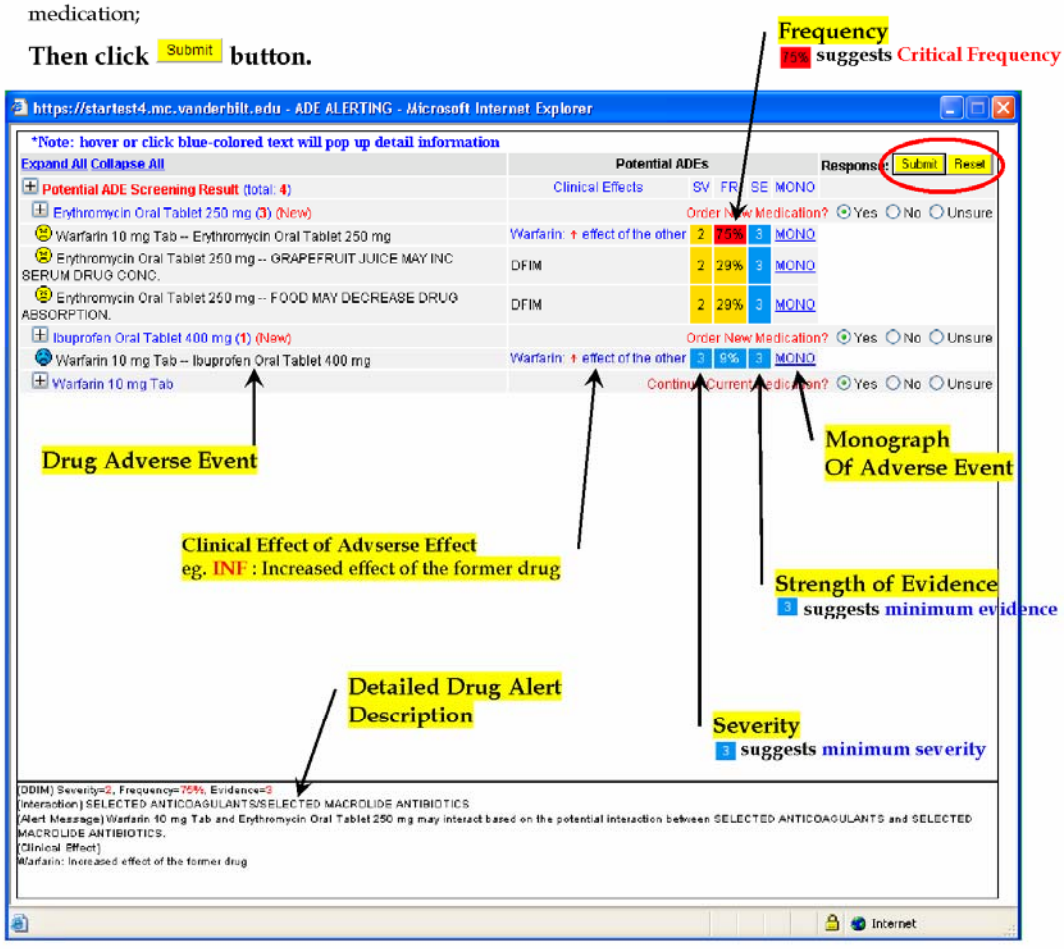
6) You should see a button [Click Here to Display Potential ADEs] on the yellow area under the [Rx] tab. Click that button;

7) Review the screen, available drug alert information includes:

severity	**clinical effect**
frequency	**monograph**
strength of evidence	**interaction**
alert message	**advice**

And based on your review, decide whether or not to order the medications. Press the appropriate choice (Order New Medication Yes No Unsure, Continue Current Medication Yes No Unsure) for each medication;

Then click [Submit] **button.**



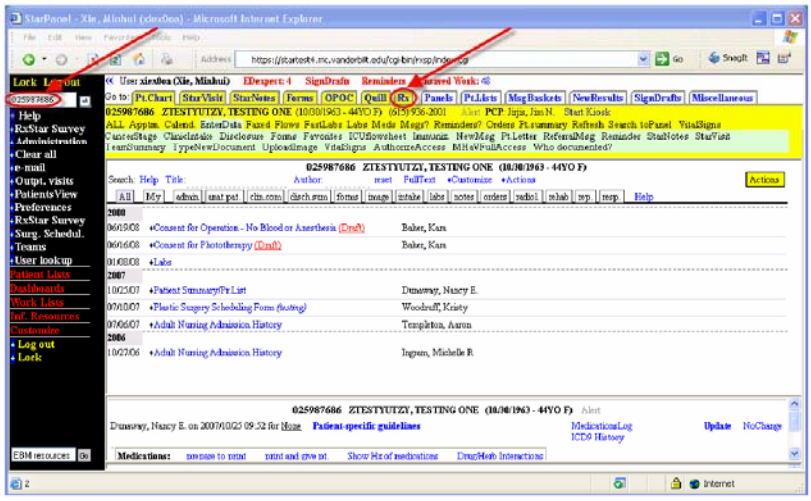
8) Turn to the next page when you finish.

2nd Training Case – Instruction Sheet for MR# 025987686 Page # 3

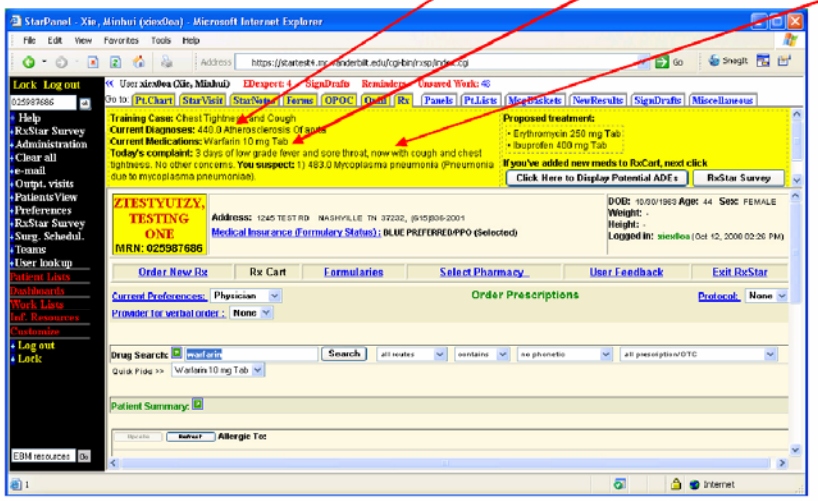
1) Now you are still in StarPanel; Otherwise, please re-login using your username and password;

2) Pull up the patient chart MR# 025987686 named "Ztestyutzy, Testing One";

3) **Now, click the Rx tab to start RxStar;**



4) Review this patient's profile including "**Current Diagnosis**", "**Current Medications**", "**Today's Complaint**" under the Rx tab;



5) Using RxStar, search for Erythromycin, Ibuprofen respectively; and add the prescriptions for:
   Erythromycin 250 mg Tab, tid, 14 days
   Ibuprofen 400 mg Tab, bid, 14 days
   Once they are in the cart, turn to the next page

2nd Training Case – Instruction Sheet for MR# 025987686 Page # 4

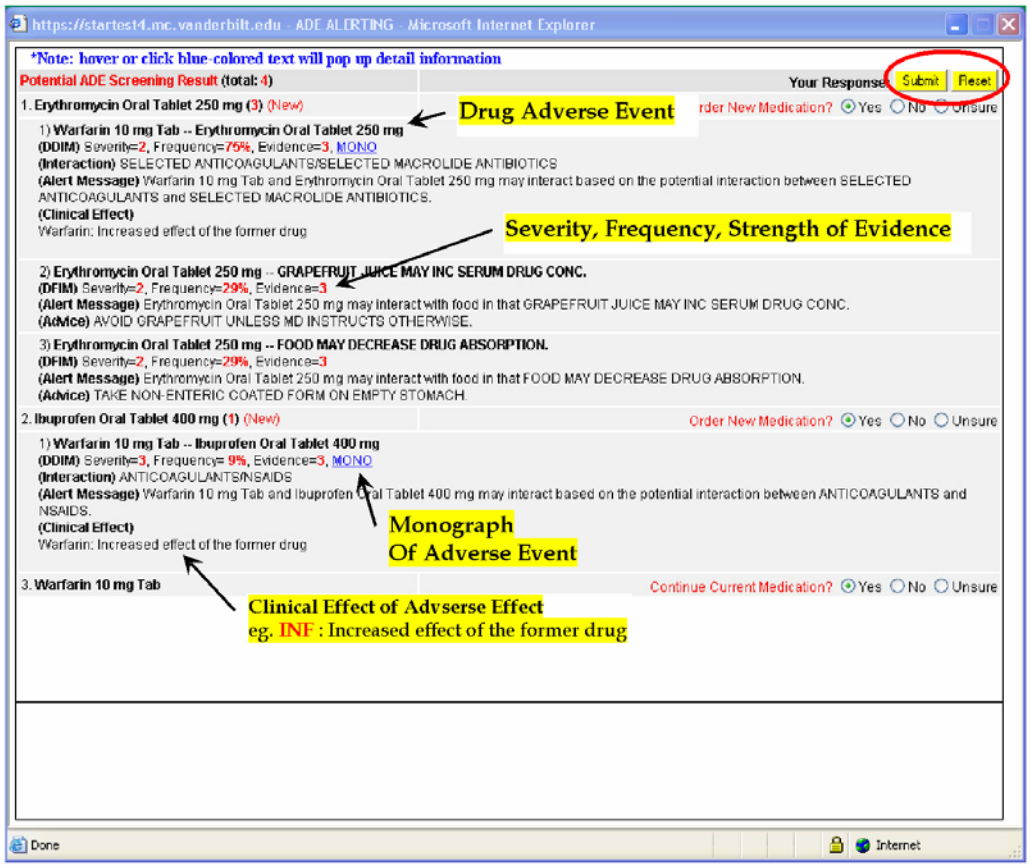
6) You should see a button [Click Here to Display Potential ADEs] on the yellow area under the [Rx] tab. Click that button;

7) Review the screen, available drug alert information includes:

severity	clinical effect
frequency	monograph
strength of evidence	interaction
alert message	advice

And based on your review, decide whether or not to order the medications. Press the appropriate choice (Order New Medication Yes No Unsure, Continue Current Medication Yes No Unsure) for each medication;

Then click [Submit] button.



8) Turn to the next page when you finish.

Instruction Sheet Before Actual Cases

You have just completed all the steps of the training case exercises. If you have questions, please let me know now. Otherwise, let's begin the actual cases.

In the following **2** actual cases, each case will be formatted like the training case, but without some of the guidance I just gave you in the training case. Please read each case, then use RxStar to try and order the medications that are suggested by the case. Use the Order New Rx button to Reset RxStar so that you don't have to relaunch it.

Please turn the page to begin the actual cases.

1st Actual Case - Instruction Sheet For MR# 025987702

1) Now you are still in StarPanel; Otherwise, please re-login using your username and password;

2) Pull up the patient chart **MR# 025987702** named "**Ztestyutzy, Testing Two**";

3) **Now, click the Rx tab to start RxStar;**

4) Review this patient's profile including "**Current Diagnosis**", "**Current Medications**", "**Today's Complaint**" under the Rx tab;

5) Using RxStar, search and add the prescriptions for:

Nexium Oral Capsule, Delayed Release(E.C.) 40 mg, tid, 14 days
Itraconazole Oral Capsule 100 mg, bid, 14 days
Fluoxetine Oral Capsule 20 mg, tid, 14 days
Zolpidem 10 mg Tab, daily, 14 days

Once they are in the cart, go to next step;

6) You should see a button Click Here to Display Potential ADEs on the yellow area under the Rx tab. Click that button;

7) Review the screen, available drug alert information includes:

severity	**clinical effect**
frequency	**monograph**
strength of evidence	**interaction**
alert message	**advice**

And based on your review, decide whether or not to order the medications. Press the appropriate choice (Order New Medication Yes No Unsure, Continue Current Medication Yes No Unsure)

Then click Submit button.

8) Turn the page when you finish.

2nd Actual Case - Instruction Sheet For MR# 025987728

1) Now you are still in StarPanel; Otherwise, please re-login using your username and password;

2) Pull up the patient chart MR# 025987728 named "**Ztestyutzy, Testing Three**";

3) **Now, click the Rx tab to start RxStar;**

4) Review this patient's profile including "**Current Diagnosis**", "**Current Medications**", "**Today's Complaint**" under the Rx tab;

5) Using RxStar, search and add the prescriptions for:

Digoxin Oral Tablet 125 mcg, tid, 14 days
Enalapril Maleate 10 mg Tab, bid, 14 days
Spironolactone Oral Tablet 50 mg (Aldactone) , tid, 14 days
Zolpidem 10 mg Tab, daily, 14 days

Once they are in the cart, go to next step;

6) You should see a button Click Here to Display Potential ADEs on the yellow area under the Rx tab. Click that button;

7) Review the screen, available drug alert information includes:

severity	clinical effect
frequency	monograph
strength of evidence	interaction
alert message	advice

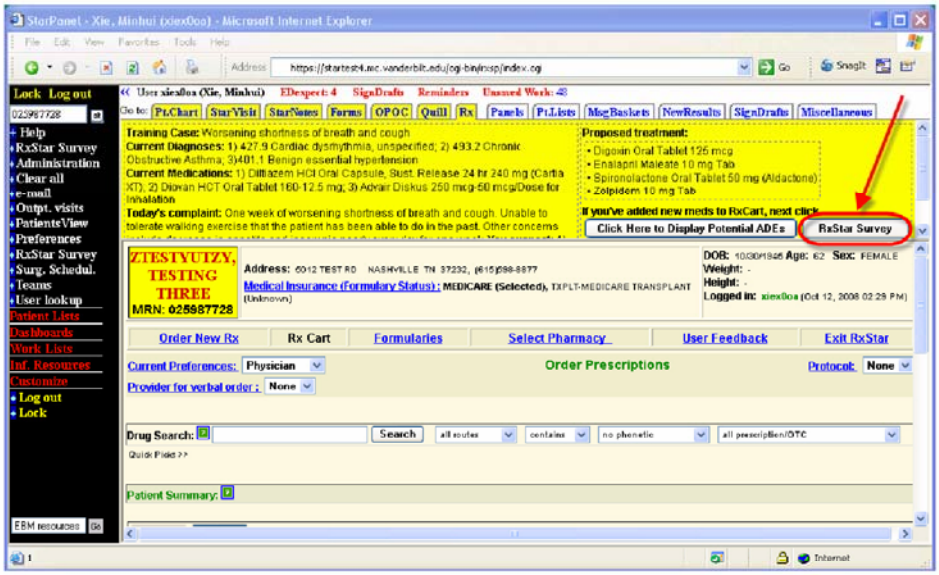
And based on your review, decide whether or not to order the medications. Press the appropriate choice (Order New Medication Yes No Unsure, Continue Current Medication Yes No Unsure)

Then click Submit button.

8) Turn the page when you finish.

Instruction Sheet For Survey

Thank you! Now please complete the survey:



1) You should see a button RxStar Survey on the yellow area under the Rx tab. Click that button;

2) Fill out survey questions and enrollment form, then click Submit button.

You have completed RxStar survey study.

Thank you!