Challenge Project Part 2 Statement of Work

Electronic Health Record Usability Evaluation and Rating

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In the Charter for this Challenge Project, the author reviewed a substantial amount of data demonstrating that poor usability represents one of the most, if not the most significant barrier to the adoption of electronic health records (EHR's) (Belden et al., 2009). Usability assessment is now becoming widely recognized as a critical factor in the implementation and success of interactive clinical information systems (Jaspers, 2009; Smelcer et al., 2009). Methodological research has validated a number of techniques for obtaining accurate, reproducible measurements of various usability parameters. These include expert heuristic evaluation (Kamper, 2002; Tang et al., 2006), cognitive task analysis (Schachak et al., 2008), cognitive walk-through (Peute and Jaspers, 2007; Liu et al., 2005), "think aloud" system testing (Jaspers et al., 2004), and user surveys (Bastien, 2010). However, as traditionally applied, all these methods usually require complex, structured testing procedures executed by a highly trained tester interacting with clinician subjects in an isolated laboratory setting. It was felt that this would create enough scheduling and work burden on test subjects to deter participation by the busy clinicians whose input was most needed and might fail to uncover significant usability problems that would arise in more natural uncontrolled settings. The proposed solution was to develop a relatively inexpensive EHR usability rating application sufficiently portable, standardized and straightforward to be presented in a self-contained format such as a laptop or tablet computer and used independently by clinicians at times convenient to them and in settings that mimic the interruptions and changing work priorities of a typical clinical environment.

Draft Scope

According to the International Organization for Standardization (ISO), “Usability is the effectiveness, efficiency and satisfaction with which specific users can achieve a specific set of tasks in a particular environment (Schoeffel, 2003).” As reviewed in the Project Charter, the

Health Information Management Systems Society (HIMSS) EHR Usability Task Force (Belden et al., 2009) developed this principle into five factors which can be used to objectively evaluate usability and measure user performance in an EHR application: efficiency, effectiveness, ease of learning, cognitive load, and user satisfaction. To measure these factors, the proposed application will leverage recently developed automated mobile usability analysis tools capable of recording, organizing, and reporting every detail of the interaction between a user and an application including all mouse clicks, timings, desktop activity, screen appearances, and a full audio and video record of the user at work (e.g. MORAE, 2012 and see also Bastien, 2010 p. e20). Such systems are also capable of administering user satisfaction questionnaires at the completion of the testing session. Important events can be flagged as they occur and metrics can be calculated automatically, dramatically decreasing the work required for analysis. As clinician users work a set of commonly encountered clinical scenarios, the analytic tools will be used to measure the time necessary to complete important tasks (efficiency), the accuracy in completing important tasks, (effectiveness), and the perceived effort necessary to complete important tasks (satisfaction). Because of space constraints, the rest of the discussion will focus on these three of the five HIMSS usability metrics.

For use in the scenarios, the application designers will construct a database of 100 imaginary test patients with data available on each patient to include demographics, payer information, problem list, allergy list, medication list, and flow sheets of representative laboratory data. The database will be constructed in Oracle, Microsoft SQL, and comma delimited (CSV) text formats, which should allow sufficient flexibility for import into most testing systems. A similar database was constructed in the author's own practice for training use when the current office EMR was implemented in 2007, so this is known to be feasible. The

design team will also construct a library of clinical scenarios representing important tasks clinicians commonly wish to accomplish using EHR's. The HIMSS and the National Institute of Standards and Technology (NIST) have published model scenarios and enumerated the EMR-specific tasks involved in completing each of them. A typical outpatient scenario and task list from the HIMSS (Grayson et al., 2010, p. 17) would be:

New patient presents with 3 days of dysuria, hematuria, urgency and frequency. No fevers, chills, or back pain. Physician orders Bactrim DS 1 tab bid x 3 days, phenazopyridine 200 mg tid after meals. Two days later, patient phones in that she has an itchy rash between the toes of her left foot. Physician recommends OTC terbinafine cream to apply bid x 10 days.

A typical inpatient scenario and task list from the NIST (Schumacher et al., 2011, p. 82) would be:

Patient is a 45-year-old African-American female living in an urban center. She has hypertension (HTN), obesity, Type 2 Diabetes, elevated cholesterol (LDL), and asthma. She started smoking when she was 17 years old and is actively trying to quit. The patient is brought to the Emergency Room by Emergency Medical Services. She called 911 when she was having chest pain

Using similar techniques, the design team will initially construct a panel of 10 inpatient and 10 outpatient scenarios with associated structured lists of the tasks necessary to complete each one. As clinicians log in to the EMR under study and work the scenarios, the monitoring application will capture the time for each task, time for the whole scenario, and task accuracy as indicated by number of correct clicks, use of the back button, number of pauses to decide what to do next, and the number of tasks completed successfully. At the end of a session, the user will complete a questionnaire, ranking several aspects of the EMR system's ability to support clinical task completion and decision making on a scale of one to five and allowing the calculation of a satisfaction score. An example of such a survey form can be found in Grayson et al., 2010, p. 25-26. The application will keep a complete audio and video record of each session and users will know that they can "think aloud" during testing if they wish. The application will also provide

customization tools for end-users to add test patient data, clinical scenarios, and survey instruments to make the program more useful and effective at their specific institutions.

The proposed application could easily reside and run on an Intel core i5 based Windows laptop computer with 8 GB of RAM, a one TB hard drive, a webcam, and a microphone, a configuration that can be obtained for less than $800. The MORAE recording and analytics software bundle costs $1,495, and additional copies of the recorder module are available for $195. Discounts are available for government, nonprofit, and educational organizations. This laptop configuration could be utilized for testing anywhere there is a connection to a hospital or physicians' office computer network or even over the internet (Jaspers, 2009).

Objectives

Poor usability represents the greatest barrier to the widespread adoption of electronic health records (Belden et al., 2009). In addition, an accumulating body data suggests that the simple adoption of EHRs does not produce the improvement in patient care quality and safety that early studies predicted (Lindner et al., 2007; Zhou et al., 2009). Overly rapid adoption of poorly designed systems can even lead to an increase in medical errors and a decrease in patient safety (Warden et al., 2011). Classen and Bates (2011) observed:

> *Our health care system needs tools for evaluation of these systems when they are operational, not just before implementation…Such self-assessment tools could be developed and implemented with the use of simulation approaches similar to the way the Leapfrog Group assessment tool for EHR's and clinical decision support has been used.*

The proposed inexpensive, portable, rapidly deployable usability evaluation system is just such a tool. The goal is "to knock down barriers to innovation in healthcare IT (Startup America Policy Challenge, 2012)." Specific project objectives include:

- Identify and correct EMR design weaknesses that can lead to user errors and threats to patient safety.
- Motivate large numbers clinicians to participate in ongoing testing and review of EHR's.

- Accumulate reproducible quantitative data to guide vendors' understanding of how to improve product design in this area.
- Inform the purchasing decisions of clinicians and healthcare organizations so that competition will motivate vendors to improve performance in this area.
- Stimulate the development of more logical, powerful, intuitive EHR's which support clinician workflows, genuinely increase clinician efficiency and productivity, and thereby improve the safety and quality of patient care.
- Overcome the usability barrier to EMR adoption

In his own small community, the author is acquainted with well over 100 physicians who are enraged over the dysfunctional health IT products being forced on them. The large volume of informatics research published on this topic over the last three years confirms that this is a national problem. In the February 8, 2012 edition of the *Journal of the American Medical Association*, Wang and Huang (2012) said of current generation EHR's "Costs are passed down to healthcare organizations in terms of dollars, clinicians in terms of time, and consumers in terms of [loss of] face-time with clinicians, with a few improvements in utility." Although there are no formal studies as yet, the author predicts that large numbers of clinicians will make use of this tool and that data accumulation will be rapid.

Resources and Timetable

The hardware and principal performance monitoring software are already available "off the shelf." Additional work to complete the application will include constructing the sample patient and scenario libraries and task lists, writing the user satisfaction survey documents, writing the software and interface to present user instructions, help, and survey instruments, and writing the software to package and store test session results in a standard format which allows the results of multiple testing sessions to be combined and statistically analyzed. A team of three experienced physicians and three information technology/programming experts should be able to produce a working application in six months. Time will be required for qualification and recruitment of test participants, for alpha and beta testing and for validation testing in

comparison to more established usability evaluation systems. Research so far has shown that usability testing with automated data collection systems is an effective alternative to the more traditional laboratory-based testing methods (Bastien, 2010). Even with the additional development and testing time, a viable release candidate could be produced within a year.

Risk

As discussed in the Project Charter, one risk to the development and distribution of a convenient, low cost usability testing application is the possibility of strong opposition from EMR vendors. A flood of data and new demands from their customer base will add complexity and expense to their development process. One way to overcome this is simple communication, where users reach out to vendors and enlist their cooperation in a collaborative effort to focus on usability and improve EMR products more rapidly. If the vendors are truly committed to using their technology to improve healthcare safety, quality, and efficiency, they should be open to such a cooperative approach.

A second risk is that the proposed application might conflict with or duplicate the usability evaluation process currently being designed into the stage 2 Meaningful Use (MU) criteria. Because the application will largely be applied at a later stage of EHR development than MU certification and will be more easily customizable to evaluate specific local EMR implementations on-site, it will provide additional functionality and should complement rather than oppose the MU testing process.

Because the application is intended as an end-user product which tests but does not alter EMR systems, it should not necessarily be subject to any laws or government regulations. However, government regulations have a large impact in this area. The arbitrarily short time schedule for obtaining large MU incentives is diverting vendor resources and attention from

necessary innovation in EMR development and forcing healthcare organizations to implement EMR systems with significant potential to increase medical errors, decrease clinician efficiency and productivity, and even threaten patient safety (Warden et al., 2011; Classen and Bates, 2011). The Office of the National Coordinator (ONC) and the Center for Medicare and Medicaid Services (CMS) have not been receptive to modifying the schedule. Some physicians have started to consider political action, asking their Senators and Representatives to introduce legislation directing ONC and CMS to delay the deadline for implementing at least the CPOE portion of stage 1 MU criteria until further usability testing and product redesign improves EHR performance in this area. A rapid, portable, inexpensive usability testing system could certainly play a role in this process.

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