

## Towards a Usability and Error “Safety Net”: A Multi-Phased Multi-Method Approach to Ensuring System Usability and Safety

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### Abstract

*The usability and safety of health information systems have become major issues in the design and implementation of useful healthcare IT. In this paper we describe a multi-phased multi-method approach to integrating usability engineering methods into system testing to ensure both usability and safety of healthcare IT upon widespread deployment. The approach involves usability testing followed by clinical simulation (conducted in-situ) and “near-live” recording of user interactions with systems. At key stages in this process, usability problems are identified and rectified forming a usability and technology-induced error “safety net” that catches different types of usability and safety problems prior to releasing systems widely in healthcare settings.*

### Keywords:

User-Computer Interface; Patient Safety, Health Information Systems

### Introduction

Ensuring the usability and safety of healthcare IT is essential in order to lead to successful adoption of healthcare IT. In recent years, the issue of poor usability of many healthcare IT systems has come to the fore [1,2]. Indeed, in healthcare there are continued reports of end user dissatisfaction with systems and reports of serious usability problems. In addition, implementation failures due to usability issues and negative impacts of some systems on clinical workflow continue to be reported [3]. In recent years, poor usability has also been closely linked with the occurrence of technology-induced error. Technology-induced errors have begun to be studied more widely in health informatics and represent a class of errors that emerge when IT is deployed and used in complex healthcare settings [4]. Such errors are difficult to find using traditional software testing methods (e.g. white- and black-box testing) and in many cases are only detectable (given conventional testing methods) when healthcare IT is operational in real healthcare contexts [4].

Many different approaches have been proposed and applied for testing the usability of systems and for evaluating their impact on patient safety. Each method has its advantages and disadvantages. For example, basic usability testing can be used to detect surface level usability problems with healthcare IT but may not be sufficient to assess how a system affects clinical workflow (e.g. real patient encounters) or complex clinical decision making and reasoning. In contrast, methods such as clinical simulation may allow for analysis of the

impact of systems on clinical work activities but may not detect basic usability problems. Therefore, a multi-method approach may be needed to ensure system usability and safety prior to release. Furthermore, integrating different methods in a multi-phase approach holds promise for obtaining the full benefits of the different methods. In this paper we will describe a methodological framework for developing a “safety net” approach to detecting and rectifying usability problems and potential technology-induced error prior to widespread release of healthcare IT. It will be argued that the methods described in this paper need to be considered not only in the context of system design (e.g. during one-time design of vendor-based systems), but also in subsequent implementation of commercial systems (e.g. implementation of vendor products, such as electronic health records (EHRs) in hospital settings). As will be described, the methodological approach outlined in this paper has been successfully applied to both improving the design of healthcare IT developed by developers and vendors, as well as assessing the usability and safety of completed healthcare IT deployed in healthcare organizations.

### Methods

A process for testing healthcare IT was developed by the authors and involves several phases described below. In the first phase, rapid low-cost usability testing is conducted. Video recording is used to collect data on typical user interactions, where users are recorded while carrying out representative tasks using a system under study [5]. Analysis of the resultant video data is facilitated by using principled coding schemes and computer coding tools. This is followed by a phase of testing under simulated conditions (i.e. by applying clinical simulation methods). Where possible, this is then followed by testing of live, or near-live clinical interactions, where users are observed under close-to-real or real conditions and settings [6]. After fixing errors and problems detected at each of these stages, the system is eventually released for widespread deployment.

The authors have employed the approach described above in the design and development phases of the system life cycle as well as for testing and modifying vendor-based systems that were purchased by healthcare organizations prior to their widespread deployment. The intent is to form in essence a usability and error detection “safety net” that can catch different types of usability problems and errors before a system is released on a widespread basis. Details of our methodological approach are described below.

### Phase 1. Low-Cost Rapid Usability Testing

The detection of major surface level usability problems is key to ensuring overall system usability and safety, and although not sufficient on its own to ensure system safety, it is a critical first stage. An approach we have developed and applied is termed "low-cost rapid usability engineering" [5]. Using this approach, free or low-cost screen recording software is installed on computers used in the testing. Participants (e.g. health professionals, patients etc.) are asked to carry out representative tasks using the system under study. The interactions of the study participants are recorded (i.e. screen recording, audio recording and video recording of physical actions) in their entirety. Participants may also be asked to "think aloud" or verbalize their thoughts while interacting with the system. Approaches may include collecting user interaction data (e.g. computer screen interactions as movie files) along with audio of participant verbalizations. This approach to usability testing has been used in many studies and in our approach constitutes the first phase of the "safety net."

### Phase 2. Error Correction from Usability Testing

The data collected in Phase 1 consists of digital screen recordings of one or more users (i.e. study participants) interacting with a system under study while verbalizing their thoughts [7]. One approach to accelerating the process of analyzing this data has been to use predefined coding schemes, such as the one developed by the authors that provides categories of commonly detected usability issues [8]. Such schemes (in conjunction with video coding tools) allow for replay of the video data and coding of that data for key usability problems in close to real-time [5]. Identified usability problems are prioritized and presented to the development or implementation team in the case of vendor-based systems being deployed in healthcare settings. Decisions regarding which issues or problems to rectify at this point are discussed with the IT staff, taking into account the severity of the problems as well as other contingencies such as the release schedule and resources for modifying the system. In a number of our studies, we have found this stage to have a quick turnaround time, but system modifications may need to be restricted to fixing problems considered most urgent or severe. At this stage, issues identified are typically surface level usability problems.

### Phase 3. Clinical Simulation

From our early experiences, it was found that Phase 2 usability testing alone is not enough to ensure the usability and safety of healthcare IT. As a consequence, the authors and colleagues have worked on developing low-cost rapidly-conducted clinical simulations [4]. We have defined clinical simulations as an extension of usability testing that includes not only observing representative users doing representative tasks, but also testing in representative or real environments (e.g. clinics with real or realistic workflow) [9-12]. This may involve using real (or realistic) testing scenarios in testing. Clinical simulations in our work have varied from use of actors to development of digital video patients used in testing interactions involving real or highly realistic tasks and workflows. For example, a clinical simulation may involve participants (e.g. physicians) interviewing a simulated patient while using a new electronic health record system or decision support tool to enter and record patient data. Data collection involves video and audio recording of all user interactions with systems under study.

### Phase 4. Error Correction from Clinical Simulation

The analysis of the data collected from clinical simulations (e.g. video and audio data) is similar to that of the analysis of usability testing data. However, at this phase, the focus of analysis is typically on assessing the impact of systems on clinical workflow and healthcare activities. Coding schemes we have employed at this phase include categories for assessing impact of systems on decision making, reasoning, physician question asking, and also categories for identifying potentially negative impact such as increased time to complete tasks and workarounds that are potentially dangerous. In addition, from our experience we have found that surface level usability problems not detected from Phase 1 testing may also end up being identified in this stage. Major defects (e.g. negative system impact on clinical workflow) identified from clinical simulation are corrected, where feasible, before moving on to the next phase.

### Phase 5. Near-Live Testing

In a number of studies we have conducted, after clinical simulation has been completed, we have moved to observe and record a limited number of user interactions with the system in a live setting, prior to widespread deployment or release [6]. This limited naturalistic testing involves setting up unobtrusive recording equipment (e.g. using free screen recording software installed on systems used) and allows us to collect data on use of the system in real contexts prior to full-scale product release or healthcare organization implementation. Issues at this stage include obtaining institutional review board consent for collecting data that may involve real patients. Whether this additional level of testing is feasible depends on gaining organizational access to settings and contexts in which a system will be ultimately deployed (e.g. a hospital ward, or even an operating room off hours).

### Phase 6. Error Correction from Near-Live Testing

From our work we have found that limited naturalistic testing almost invariably uncovers further issues that could not have been found from usability testing or clinical simulation alone. Major concerns or issues that are identified are brought to the attention of the design/implementation teams, with problems warranting immediate fixing being rectified prior to widespread system release.

### Phase 7. Widespread Deployment and Continual Monitoring

Upon completion of the phases described above, the system can be released on a wide scale with greater confidence that major issues have been detected before "going live". This may involve releasing a healthcare IT software product to the market, or the widespread deployment of a vendor system throughout a hospital or health region. Continual monitoring of system use, in terms of possible usability problems or errors, is recommended. As shown in Figure 1, the safety net approach can be considered a cyclic process, with each phase leading to the correction of different types of errors. Figure 1 also shows the need for continual error monitoring (and correction), once the system is in use.

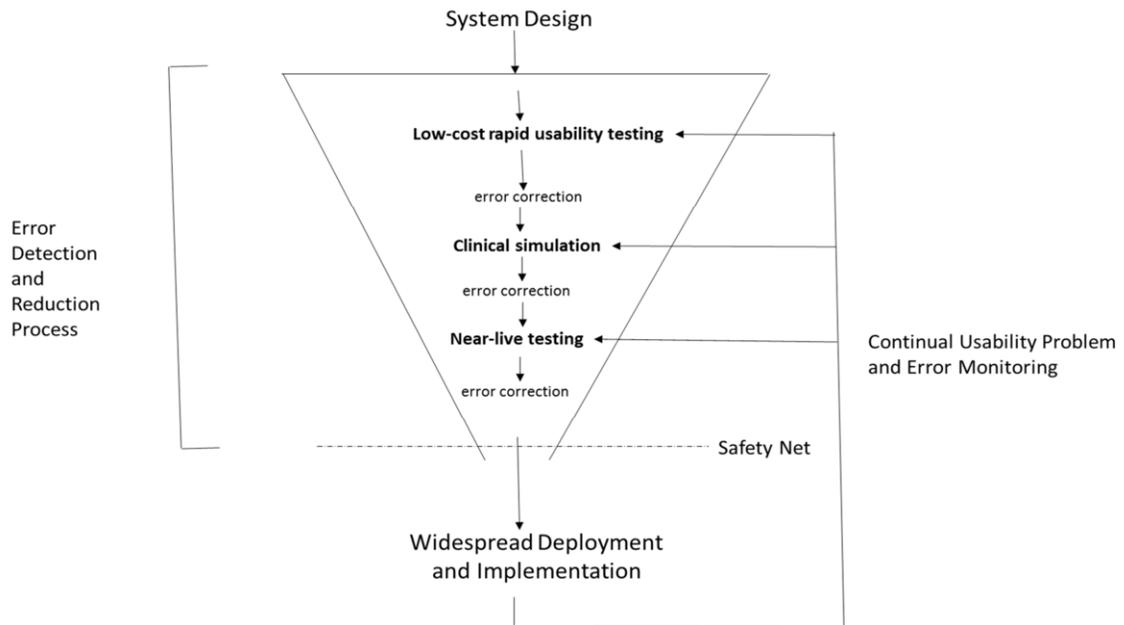


Figure 1—A safety net approach for usability problem and error detection.

In Figure 1 we can also see that the approach attempts to identify and rectify as many usability problems and errors as possible before widespread deployment and implementation. At the top of Figure 1, we can see that after initial system design is complete, low-cost rapid usability testing can be employed to correct surface level usability problems. This is followed by clinical simulation and near-live testing. At each stage different types of errors are identified, with surface level usability problems typically detected during low-cost rapid usability, while issues around workflow are more likely to be detected in subsequent phases. The dotted lines in Figure 1 illustrate the “sieve” part of the safety net, which is designed to catch as many errors as possible before a system goes to widespread deployment, as illustrated in the lower part of Figure 1. Once deployed, continual monitoring for usability and feedback from error reports from end-users may need to iteratively trigger further cycles of usability analyses, as indicated by the arrows in the right side of Figure 1.

## Results

We have applied the multi-method, multi-phased approach described in this paper in a number of assessments of EHRs, decision support systems (DSSs) and mobile health applications. A finding emerging from our work is that the types of errors and usability problems detected at each phase are different, and that therefore, a multi-phased approach was needed to detect the widest possible range of problems. For example, early phase usability testing (in Phase 1) typically uncovered surface level usability problems, while testing

involving clinical simulations (Phase 2) typically detected issues related to impact on clinical workflow, including identifying potentially dangerous workarounds. In Phase 3, near-live testing typically revealed a range of contextual issues that would not have otherwise been predicted by the previous phases. It should also be noted that surface level usability problems (and even software programming errors not caught by traditional white- and black-box testing) were typically detected throughout all phases of the approach (i.e. even during clinical simulations and live or near-live testing, usability problems would still be detected that had not been found in Phase 1). The approach thus provided a usability and technology-induced error “safety net”, without which serious usability problems and errors would have found their way into actual system use and patient care.

In development and refinement of healthcare IT during the design and prototyping phases, our early work employed components of the approach described in this paper, specifically classic usability testing of an EHR was followed by clinical simulation of a commercial EHR system, where actors played the part of a patient while study participants (e.g. physicians) interacted with the system to handle patient cases [13].

In more recent work, we are adapting some of the approaches described in this paper to the testing of a novel, composable user interface designed to allow for near-live testing using remote usability engineering methods [14]. This will take place in two phases, the first being detailed, comparative, in-person, near-live testing in crossover studies of commercial and experimental systems, in which the user is asked to create interfaces in the composable system, and both systems are

evaluated as to user behavior and diagnostic accuracy. Another phase is testing larger numbers of subjects via remote near-live testing, in which software working in the background records user actions and generates a video. The ability to send users a link and have them perform tests at a distance, without in-person meetings, allows for larger numbers of subjects and testing of sharing functionality, which is expected to yield new insights about composable systems and clinician cognitive processes and communication.

The approach described in this paper has also been applied to ensure that the implementation of vendor-based products (e.g. EHRs) as well as their extensions (e.g. addition of decision support capabilities to an EHR) do not inadvertently introduce serious usability or safety issues when implemented in hospitals. Along these lines, we have successfully employed parts of the approach as well as the full approach on a number of projects. In one study, we employed the full multi-phased approach in the implementation of clinical guidelines within a commercial EHR product [6]. In Phase 1 of the approach described in this paper, basic usability testing was conducted. This testing identified a range of surface level usability problems, such as navigational issues, consistency problems and the need for improved layout and wording of alerts. This included the need to relabel alerts that appeared on the screen and to make them more conspicuous to the physician's eye (these issues were rectified in Phase 2). In Phase 3, a clinical simulation was conducted involving participants (8 physicians) interviewing a simulated digital patient (from which they could ask for patient information) in order to assess the impact of the system on clinical workflow. Analysis of the video data from these simulations (conducted in Phase 4) indicated the introduction of the guidelines inadvertently changed physician workflow in a number of unexpected ways. For example, some participants found that the alerts were triggered too early, before the participant had a chance to review the patient's information and data. As a result, alert triggering mechanisms were modified during Phase 4. In Phase 5, limited naturalistic testing was conducted and defects detected from this phase were rectified in Phase 6, prior to widespread release of the guidelines. A subsequent clinical trial showed a high rate of uptake of the guidelines by end-users in the hospital, in large part due to the multi-phased multi-method testing that was conducted prior to system release.

In another application of the approach, we employed these methods in the assessment of a medication administration system in a Japanese hospital. Phase 1 testing involved having 16 physicians and nurses interact with the system to carry out medication tasks while being video recorded. Phase 1 identified a number of specific usability problems, while issues with workflow as a result of the system (as well as potential technology-induced errors) were identified in Phase 3 using clinical simulations. In terms of problems at the workflow level, it was found that the system was inflexible and rigid during emergency situations, when there was a need to override the systems due to time constraints. Results of the phased multi-method approach led to refinement of the system to include emergency overrides, improved workflow and streamlined usability during the defect correction phases of the process [15].

## Discussion

In our work we have integrated a number of methods for ensuring system usability and safety. We found that each phase of this method detected different types of problems,

starting with surface level usability problems and leading to issues related to workflow, impact on physician cognitive processes, and patient safety. It is argued that such a multi-method phased approach is needed to create a "safety net" to detect and rectify a range of errors and problems prior to widespread system release. The approach described in this paper is beginning to be applied in healthcare organizations where usability and safety have been deemed of utmost importance in system implementations and deployments. Current areas we are working on include streamlining the methods and processes involved to shorten the time taken for analysis (using published coding schemes and computer tools) and increasing dissemination of the approach through demonstration projects at key healthcare organizations worldwide.

## Conclusions

The usability of healthcare IT continues to be a problem, with reports of systems that are unusable and in some cases unsafe. One approach has been the development of guidelines and regulations to improve the situation [17-19]. In another direction, to address these issues, the authors have developed a methodological approach that involves several phases of data collection and analyses. This approach begins with low-cost rapid usability testing, followed by a phase of clinical simulation and finally near-live or live testing involving a limited number of participants. Our experiences with this approach has indicated that by applying this "safety net" approach, a wide range of issues and problems can be detected (and rectified) prior to widespread release of healthcare IT systems. Areas of future work include demonstrating the cost-effectiveness of the approach and disseminating information about it more widely. This method can become incorporated in healthcare IT practice as there is a need to enhance patient safety through improving the usability of healthcare IT.

## Acknowledgements

This work is supported by the Agency for Healthcare Research and Quality (AHRQ) grant R01HS023708.

## References

- [1] B. Middleton, M. Bloomrosen, M.A. Dente, B. Hashmat, R. Koppel, J.M. Overhage, T. H. Payne, S.T. Rosenbloom, C. Weaver, J. Zhang, Enhancing patient safety and quality of care by improving the usability of electronic health record systems, *J Am Med Inform Assoc* **20** (2013), e2-8.
- [2] A.L. Kellermann, S.S. Jones, What it will take to achieve the as-yet-unfulfilled promises of health information technology, *Health Affairs* **32**(1) (2013), 63-68.
- [3] E. Jamoom, P. Beatty, A. Bercovitz, et al. Physician adoption of electronic health record systems: United States, NCHS data brief, no. 98. Hyattsville, MD. National Center for Health Statistics, 2012.
- [4] E. Borycki, A. Kushniruk, C. Nohr, H. Takeda, S. Kuwata, C. Carvalho, M. Bainbridge, J. Kannry, Usability methods for ensuring health information technology safety, *Yearb Med Inform* **8**(1) (2013), 20-27.
- [5] A.W. Kushniruk, E.M. Borycki, Low-cost rapid usability engineering: designing and customizing usable healthcare information systems, *Health Q* **9**(4) (2006), 98-100.
- [6] A.C. Li, J.L. Kannry, A. Kushniruk, D. Chrimes, T.G. McGinn, D. Edonyabo, D.M. Mann, Integrating usability testing and think-aloud protocol analysis with "near-live" clinical simulations in evaluating clinical decision support, *Int J Med Inform* **81**(11) (2012), 761-72.
- [7] A.W. Kushniruk, V.L. Patel, Cognitive and usability engineering methods for the evaluation of clinical information systems. *J Biomed Inform* **37**(1) (2004), 56-76.

- [8] A. Kushniruk, E. Borycki, Development of a video coding scheme for analyzing the usability and usefulness of health information systems. *Stud Health Technol Inform* **218** (2015), 68-73.
- [9] E. Borycki, E. Keay, Methods to assess the safety of health information systems, *Healthc Q* **13** (2010), 47-52.
- [10] A.W. Kushniruk, C. Nohr, S. Jensen, E.M. Borycki, From usability testing to clinical simulations: Bringing context into the design and evaluation of usable and safe health information technologies, Contribution of the IMIA Human Factors Engineering for Healthcare Informatics Working Group, *Yearb Med Inform*, 2012 Dec;8:78-85.
- [11] S. Jensen, S.L. Rasmussen, K.M. Lyng, Use of clinical simulation for assessment in EHR-procurement: design of method, *Stud Health Technol Inform* **192** (2013), 576–80.
- [12] A.W. Kushniruk, E.M. Borycki, S. Kuwata, J. Kannry, Emerging approaches to usability evaluation of health information systems: towards in-situ analysis of complex healthcare systems and environments, *Stud Health Technol Inform* **169** (2010), 915-919.
- [13] V.L. Patel, A.W. Kushniruk, S. Yang, S., J.F. Yale, Impact of a computer-based patient record system on data collection, knowledge organization, and reasoning, *J Am Med Inform Assoc* **7**(6) (2000), 569-585.
- [14] B. Albert, T. Tullis, D. Tedesco, Beyond the usability lab: Conducting large-scale online user experience studies, Morgan Kaufman, New York, 2010.
- [15] A.W. Kushniruk, E.M. Borycki, S. Kuwata, J. Kannry, Predicting changes in workflow resulting from healthcare information systems, *Healthc Q* **9** (2006), Oct 15:9(Sp).
- [16] National Institute of Standards and Technology, Health IT Usability, Accessed (November 8, 2016) from: <http://www.nist.gov/healthcare/usability/>
- [17] Agency for Healthcare Research and Quality, EHR Usability Toolkit. Accessed (November 8, 2016) from: [https://healthit.ahrq.gov/sites/default/files/docs/citation/EHR\\_Usability\\_Toolkit\\_Background\\_Report.pdf](https://healthit.ahrq.gov/sites/default/files/docs/citation/EHR_Usability_Toolkit_Background_Report.pdf)
- [18] Office of the National Coordinator. Safer guides will help optimize safety. 2014 Accessed (November 8, 2016) <https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/safer-guides-optimize-safety/>
- [19] D. F. Sittig, J.S. Ash, H. Singh, ONC issues guides for SAFER EHRs. *J AHIMA* **85**(4) (2014), 50-52.

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