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Designing and Conducting Low-Cost In-Situ Clinical Simulations: A Methodological Approach

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Abstract. The need to develop more effective and usable systems in healthcare has led to increasing adoption of usability engineering methods. Primary among these methods has been usability testing, which involves observing representative users while they carry out representative tasks using health information systems. However, such testing may not capture the cognitive and social contexts of use of systems in real settings, necessitating the use of clinical simulations. Such simulations involve testing representative users carrying out representative tasks, systems in realistic and representative environments. In this paper we describe our work in both reducing the cost of simulation testing while at the same time increasing the fidelity of the simulations. We describe an approach which involves conducting simulations within real work environments and contexts as a way to achieve a high level of ecological validity. The stages involved in setting up such low-cost in-situ clinical simulations are detailed in this paper.

Keywords: Clinical simulations; usability testing; system evaluation

Introduction

It has become increasingly clear that the usability of health information systems is a major issue and that usability engineering methods need to be applied widely in the design, implementation and evaluation of health information systems. Usability testing typically involves observing representative users (e.g. health professionals) while they interact with an information system under study (e.g. a medication administration system) to carry out representative tasks using the system (e.g. medication order entry) [1]. While recommendations based on usability testing have led to improvements in the usability of many health information systems, there are still many reports of systems being released that are not usable, do not match user information needs and that do not fit into the complex workflows of healthcare situations in which they are deployed [2]. In this paper we describe an approach that extends usability testing to clinical simulations, whereby testing not only involves representative users doing representative tasks, but also involves testing systems in representative contexts and settings typical of real-world use of the technology. In the past, simulation testing has typically involved testing systems in fixed simulation laboratories that attempt to capture the environment of real use [3]. In this paper we describe our work towards extending the fidelity of such clinical simulations further by taking such simulations

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into the actual real settings of use – i.e. by conducting the clinical simulations "in-situ" in real hospital and clinical settings using portable recording methods and approaches.

1. Background: Clinical Simulations

In order to increase the ecological validity of studies that focus on evaluating the impact of health information systems, in recent years traditional usability testing methods have been augmented by studies that more closely match real-life conditions of system use in healthcare. Among these methods are clinical simulations, where the fidelity of user interactions during testing approximates real-life situations [4-5]. This has typically involved conducting user studies in simulation laboratories which include one-way mirrors and observation rooms, where users are studied while they carry out tasks. An alternative approach has involved conducting the simulations in the actual hospital and healthcare environments where the systems will be ultimately deployed [5]. This approach argues for testing systems "in-situ" rather than testing in a site that may not be representative of the actual system use. The in-situ approach does require access to real healthcare settings, for example, access to hospital rooms or operating rooms after hours for testing, but has a number of distinct advantages. For one, the cost of setting up a simulation environment is reduced, as an "artificial" fixed laboratory environment does not need to be developed. Secondly, the fidelity of the simulation is higher when studies are conducted in a real environment. Thirdly, testing of information systems in the real setting allows for trying out systems with all interfacing technologies that would be available once the system is released there (e.g. data monitoring devices, bar-coding etc.). In addition, for some studies involving patients, it may be difficult to bring them to a fixed usability or simulation laboratory, so bringing the testing to the patients is more feasible.

2. Methodological Approach

An approach to carrying out in-situ clinical simulations is described in this section of the paper. The steps involved are based on a range of studies we have conducted and although there may be variation in the exact steps, the overall approach typically involves consideration of each of the below steps.

Step 1. Development of Test Plan: This step involves identification of the overall objectives of the evaluation, including the need for conducting the testing as a clinical simulation and the degree of fidelity (i.e. realism) required in the simulation.

Step 2. Selection of Representative Users: In this step the main characteristics of representative users (e.g. physicians or nurses etc.) of the system are identified. In the case of simulations, this typically involves not only selection of individual users, but selection of the group or team of users that will use the system to collaborate and therefore may need to be represented.

Step 3. Selection of Representative Tasks: Similar to usability testing, a set of representative tasks need to be identified that will drive the clinical simulations. However, unlike usability testing which might focus on individual tasks, for clinical simulations of real life clinical situations, tasks may focus on the

individual but they may also include tasks involving the interaction among multiple individuals (of differing types of backgrounds) working collaboratively.

Step 4. Selection of Representative In-Situ Testing Environments: This step clearly differentiates in-situ clinical simulations from usability testing as real settings and environments must be identified. Furthermore, unlike fixed laboratory simulations (which take place in a centralized simulation facility) setting up in-situ clinical simulations typically involves discussing contexts of real system use with collaborators at sites where the system will actually be deployed. In these discussions, issues related to selecting particular recording technologies and constraints such as physical space as well as specific local ethics review board requirements need to be considered. This may also require permission and support from the institution's IT staff as screen recording software may need to be deployed on the computers in a clinic where the simulation will take place, and arrangements may also need to be made for having ceiling mounted cameras put into place to record group activity during the simulation. From our experience this has typically involved one or more members of our team traveling to potential test locations and settings. Here, the team member works with local collaborators to set up a testing environment prior to data collection. This may involve setting up testing in environments like clinics in partitioned off areas or side rooms, or even in operating rooms, for conducting simulations during off hours.

Step 5. Carrying out the Clinical Simulations: The actual procedure for carrying out the simulations will depend on the constraints imposed by conducting studies in real settings (e.g. physical space, ethics requirements etc.). For example, in some settings full access to an electronic health record system and all accompanying technologies (e.g. bar coding, medication administration systems etc.) may be available for testing in the live setting. In this case the realism of the simulations involving the electronic health record can be maximized and the scenarios tested can test not only the system under study but how well it integrates with other technologies in the live setting. In other cases, the testing may be restricted to having subjects interact with a training version of an electronic health record in isolation.

Step 6. Analysis of Data: The analysis of data from clinical simulations conducted in-situ is typically similar to the analysis of video and audio that results from usability testing and is reported elsewhere [5,6]. However, the ability to test health information systems in real settings and under more realistic conditions typically leads to a richer data stream, including potentially recording screens from multiple computers, along with audio and video recording of interactions in a room setting. The analysis and coding of this data may be facilitated by using a number of computer-supported video coding tools (see [6]).

Step 7. Input into Re-design and Customization: The ultimate objective of conducting in-situ clinical simulations is to obtain detailed feedback that can be used to improve the selection, design or customization of health information systems. The results from step 6 data analysis should be summarized and presented to the relevant implementation and management teams (e.g. summary of types and frequency of coded usability or workflow problems and issues encountered under different contexts of use).

3. Experiences to Date

Our initial work in conducting clinical simulations in-situ involved a project where a medication administration system was to be tested in real clinical settings in a hospital in Japan [6]. The researchers from Canada initially planned to travel to the hospital to set up the study, but due to travel constraints, the instructions for selecting a representative hospital room and system set up were emailed to a team of collaborators at the hospital site in Japan. The recording equipment including installing Hypercam ® screen recording software on computers running the new medication administration software in a typical hospital room. In addition, the researchers in Canada worked collaboratively with their Japanese colleagues to create a list of medication entry tasks to be tried out during the simulations. In addition, to add to the realism of the simulation, a mannequin patient (with a bar coded identification bracelet) was set up in the room, so that time to do tasks such as setting up intravenous medication bags could be monitored in addition to recording interactions with the system itself. Eleven doctors and five nurses participated in the study at the Japanese site and were video recorded (computer screens as well as a recording of physical activities in the room using a camcorder on a tripod) as they carried out the medication administration tasks. After the simulations were completed participants (i.e. nurses and doctors) were interviewed about their experience using the system. The data (recordings stored on a secure hard drive) were couriered to the Canadian researchers who identified key issues from the recordings and made recommendations to the system implementation team in Japan. The recommendations included the need for implementing an emergency override function when urgency did not permit users of the system to complete the tasks.

In a recent study involving collaboration with the authors and a large American health institute, we employed the methodological approach described in this paper to test the deployment of a set of clinical guidelines [7]. These guidelines were designed to be triggered from within a major commercially available electronic health record system deployed in the New York hospital site. To assess the requirements for conducting in-situ simulation testing the first author of this paper initially travelled to the physical site in New York and worked with staff there to locate office and clinical settings where video recordings would be made. This also included working with the local IT staff at the healthcare organization to set up screen recording software on local computers. The initial simulation tasks involved having eight physician participants follow scripts that forced them through key functions of the system in order to detect basic usability problems. In a second round of simulation testing, the impact of the system on workflow was simulated by introducing a "digital patient", which consisted of a recording of a patient. This allowed the researchers to observe participants' (eight physicians) interaction with the system where they drove the interaction and where the guidelines were triggered by the participants' interactions (rather than by a fixed script). Finally, in a third condition, the recording approach was extended beyond clinical simulations to recording live interactions of physicians with the clinical guidelines (where the screen recording was triggered when guidelines were invoked). The transcripts of the audio and video from this in-situ data collection were transcribed and coded to identify ways in which the implementation of the guidelines could be optimized. This data analysis was conducted collaboratively and from a distance using skype® to share coding documentation and support collaboration between the Canadian and American researchers. From this work it was found that addressing a number of simple usability issues (such as making messages on alerts clearer and using

local medical terminology in the alerts) greatly increased the uptake of the guidelines in subsequent clinical trials. In addition, the in-situ simulation allowed for identifying issues in the local workflow involved in using the guidelines. In particular it was found some guidelines did not trigger when expected and others were automatically invoked too early or late to affect decision making. In terms of the cost-effectiveness of the approach, from this type of experience the cost of conducting such studies is reduced as compared to testing in a fixed laboratory, but the approach does typically include costs for initial travel of the investigators to the site to set up the recordings. The cost of recordings is reduced as free software can be used for that purpose, and analysis cost has been reduced by using free coding software and well-developed coding tools.

4. Discussion

To improve usability of healthcare information systems there is a need for both centralized usability testing of systems and localized testing. Centralized conformance testing and evaluation of systems is important. There is also a move towards greater application of usability engineering methods involving fixed laboratories where systems can be tested using traditional usability engineering approaches (i.e. usability testing) as well as testing involving more realistic clinical simulations. Although this is important, ensuring a system conforms to usability requirements at a centralized facility does not guarantee that when the system is released to a specific institution that the system will indeed be usable or safe. In this paper we have argued for greater use of in-situ usability testing. From our experience such in-situ testing is both cost-effective and is necessary in order to understand how an information system will fit into the complexities of real healthcare environments [7]. Furthermore, this type of testing brings the important issue of context to the fore by arguing for conducting testing not only at centralized testing facilities or in fixed laboratories, but also testing those systems within real settings where systems will be released. This supports assessing how well systems fit into local workflows and how well the systems integrate with other technologies in a real life setting [8]. We are also extending the approach for use in the selection and procurement of health information systems.

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