eClinicalWorks

EHR USABILITY TEST REPORT OF [eCLINICALWORKS VERSION 10]

Report based on ISO/IEC 25062:2006 Common Industry Format for Usability Test Reports —July 2014

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CONTENTS

1 EXECUTIVE SUMMARY

A usability test of [name of product, version, and type of EHR] was conducted on [4/12/2013 -4/19/2013] in [Westborough, MA] by [eClinicalWorks]. The purpose of this test was to test and validate the usability of the current user interface and provide evidence of usability in the EHR Under Test (EHRUT). During the usability test, [1] healthcare providers [, 1 Nurse Practitioner, and 2 non-medical users] matching the target demographic criteria served as participants and used eClinicalWorks in simulated, but representative tasks. This study collected performance data on [7] tasks typically conducted on an EHR:

- Computerized provider order entry
- Medication list
- Medication allergy list
- Drug-drug/drug-allergy interaction checks
- Electronic prescribing
- Clinical decision support
- Clinical information reconciliation

During the [40 minute] one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form (included in Appendix 3); they were instructed that they could withdraw at any time. Participants [had/have not had] prior experience with the EHR. All participants were given the opportunity to complete training similar to what a real end-user would receive prior to participating in the usability test. The administrator (Brian Hughes) introduced the test and instructed participants to complete a series of tasks (given one at a time) using eClinicalWorks. During the testing, the administrator timed the test and, along with the data logger(s) recorded user performance data on paper and electronically. The administrator did not give the participant assistance in how to complete the task. Participant screens, head shots and audio were recorded for subsequent analysis.

The following types of data were collected for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations
- Participant's satisfaction ratings of the system

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire and were compensated for their time. Various recommended metrics, in accordance with the examples set forth in the NIST Guide

to the Processes Approach for Improving the Usability of Electronic Health Records, were used to evaluate the usability of eClinicalWorks. The following is a summary of the performance and rating data collected on eClinicalWorks:

Task/Measure	N	Task Success	Path Deviation	Task Time		Errors	Task Rating 5=Easy
	#	Mean	Deviation (Observed/ Optimal)	Mean (SD)	Deviation (Observed/ Optimal)	Mean (SD)	Mean (SD)
Computerized provider order entry	4	50%	1: 1.5	112 s	71 seconds of deviation from optimal of 22 seconds	6	3.25
Medication list	4	100%	1: 1.25	127 seconds	91 seconds of deviation from optimal of 36	2	4
Medication allergy list	4	75%	1: 1.3	83 seconds	67 seconds of deviation from optimal of 16	2	4.75
Drug-drug, drug-allergy interaction checks	4	75%	1: 1.075	49 seconds	35 seconds of deviation from optimal of 14	3	3.75
Electronic prescribing	4	75%	1: 1.25	71 seconds	42 seconds of deviation from optimal of 29	1	3.75
Clinical decision support	4	100%	1:1	31 seconds	23 seconds of deviation from optimal of 8	0	5
Clinical information reconciliation	4	100%	1: 1.3	40 seconds	12 seconds of deviation from optimal of 28	3	4

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with these tasks to be: [4].

In addition to the performance data, the following qualitative observations were made:

Major findings

The software has a lot to offer; there are multiple links from which to choose to get information. All patients' information is stored by the software in one location and many functionalities are offered.

Areas for improvement

The software screen is quite busy and there are a lot of colors that are distracting somewhat to the eyes.

2 INTRODUCTION

The EHRUT(s) tested for this study was (were) [eClinicalWorks, version 10]. Designed to present medical information to healthcare providers in [Outpatient and specialty setting], the eClinicalWorks application consists of [comprehensive solutions for the next-generation healthcare IT, allowing practices to improve efficiency and enhance patient care. Using industry leading technology, eClinicalWorks will help medical practice achieve its goal of delivering the best patient care possible]. The usability testing attempted to represent realistic exercises and conditions. The purpose of this study was to test and validate the usability of the current user interface, and provide evidence of usability in eClinicalWorks. To this end, measures were captured during the usability testing of effectiveness, efficiency, and user satisfaction, such as:

- Computerized provider order entry
- Medication List
- Medication allergy list
- Drug-drug, drug-allergy interaction checks
- Electronic prescribing
- Clinical decision support
- Clinical information reconciliation

3 METHOD

3.1 PARTICIPANTS

A total of [4] participant were tested on eClinicalWorks. Participants in the test were [Community Practice Healthcare provider, Nurse Practitioner, and 2 Non-Medical Users]. Participants were recruited by [Bryan Sequeira] and were compensated for their time. In addition, participants had no direct connection to the development of, or organization producing, the eClinicalWorks EMR/PM application. Participants were not from the testing or supplier organization. Participants were given the opportunity to have the same orientation and level of training as the actual end users would have received. For the test purposes, end-user characteristics were identified and translated into a recruitment screener used to solicit potential participants; an example of a screener is provided in Appendix [1]. Recruited participants had a mix of backgrounds and demographic characteristics conforming to the recruitment screener. The following is a table of participants by characteristics, including demographics, professional experience, computing experience, and user needs for assistive technology. Participant names were replaced with Participant IDs so that an individual's data cannot be tied back to individual identities.

Part ID	Gender	Age	Education	Occupation /Role	Professional Experience	Computer Experience	Product Experience	Assistive Technology Needs
User 1	Female	23 to 39	Bachelor's Degree	Non-Medical User	2 years	Windows	Zero	No
User 2	Female	23 to 39	Master's Degree	Non-Medical User	9 months	Windows	Zero	No
User 3	Female	60 to 74	Master's Degree	Nurse Practitioner	13 years	Windows	7 years	No
User 4	Female	40 to 59	PhD/M.D.	Physician	28 years	Windows, Mac	13 years	No

[4] participants (matching the demographics in the section on participants) were recruited and [4] participated in the usability test. [0] participants failed to show for the study.

Participants were scheduled for [40 minute] sessions with [5 minutes] in between each session for debrief by the administrator(s) and data logger(s), and to reset systems to proper test conditions. A spreadsheet was used to keep track of the participant schedule, which included each participant's demographic characteristics as provided by the recruiting firm.

3.2 STUDY DESIGN

Overall, the objective of this test was to uncover areas where the application performed well – that is, effectively, efficiently, and with satisfaction – and areas where the application failed to meet the needs of the participants. The data from this test may serve as a baseline for future tests with an updated version of the same EHR and/or comparison with other EHRs provided the same tasks are used. In short, this testing serves as both a means to record or benchmark current usability, but also to identify areas where improvements must be made. During the usability test, participants interacted with [0 to 3] EHR(s). Each participant used the system in the same location, and was provided with the same instructions. The system was evaluated for effectiveness, efficiency, and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

Additional information about the various measures can be found in Section 3.9 on Usability Metrics.

3.3 TASKS

A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR, including:

- Computerized provider order entry
- Medication List
- Medication allergy list
- Drug-drug, drug-allergy interaction checks
- Electronic prescribing
- Clinical decision support
- Clinical information reconciliation

Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users. Tasks should always be constructed in light of the study objectives.

3.4 PROCEDURES

Upon arrival, participants were greeted; their identity was verified and matched with a name on the participant schedule. Participants were then assigned a participant ID. To ensure that the test ran smoothly, two staff members participated in this test: the usability administrator and the data logger. The usability testing staff conducting the test was an experienced usability practitioner with [1 year 9 month software analyst employee of eClinicalWorks with a bachelor's degree]. Each participant reviewed and signed an informed consent/release form (See Appendix 3). A representative from the test team witnessed the participant's signature. The administrator moderated the session, including administering instructions and tasks. The administrator also monitored task times, obtained post-task rating data, and took notes on participant comments. A second person served as the data logger and took notes on task success, path deviations, number and type of errors, and comments. Participants were instructed to perform the tasks (see specific instructions below):

- As quickly as possible while making as few errors and deviations as possible.

- Without assistance. Administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use.

- Without using a think-aloud technique. For each task, the participants were given a written copy of the task. Task timing began once the administrator finished reading the question. The task time was stopped once the participant indicated they had successfully completed the task. Scoring is discussed below in Section 3.9.

Following the session, the administrator gave the participant the post-test questionnaire (*e.g.,* the System Usability Scale; see Appendix 5), compensated them for their time, and thanked each individual for their participation. Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded into a spreadsheet. Participants were thanked for their time and compensated. Participants signed a receipt and acknowledgement form (see Appendix 6) indicating that they had received the compensation.

3.5 TEST LOCATION

The test facility included a waiting area and a quiet testing room with a table, computer for the participant, and recording computer for the administrator. Only the participant and administrator were in the test room. All observers and the data logger worked from a separate room where they could see the participant's screen and face, and listen to the audio of the session. To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

3.6 TEST ENVIRONMENT

The eClinicalWorks application would be typically be used in a healthcare office or facility. In this instance, the testing was conducted in [eClinicalWorks Office Headquarters in a business office setting]. For testing, the computer used a [laptop computer] running [Windows 7]. The participants used [a mouse and keyboard] when interacting with eClinicalWorks. [eClinicalWorks] used a [10 inch monitor, LCD and color display.] The application was set up by [eClinicalWorks] according to the vendor's documentation describing the system setup and preparation. The application itself was running on a [HTML/XML Format] using a [Test database] on a [Wireless Internet] connection. Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

3.7 TEST FORMS AND TOOLS

During the usability test, various documents and instruments were used, including:

1. Informed Consent

2. Moderator's

3. Post-test Questionnaire

4. Incentive Receipt and Acknowledgment Form

Examples of these documents can be found in Appendices 3-6 respectively. The Moderator's Guide was devised so as to be able to capture required data. The participant's interaction with the eClinicalWorks application was captured and recorded digitally with screen capture software running on the test machine. A [video and web (GotoMeeting)] camera recorded each participant's facial expressions synced with the screen capture, and verbal comments were recorded with a microphone.

3.8 PARTICIPANT INSTRUCTIONS

The test session was electronically transmitted to a nearby observation room where the data logger observed the test session. The administrator reads the following instructions aloud to the each participant (also see the full moderator's guide in Appendix [B4]):

Thank you for participating in this study. Your input is very important. Our session today will last about [40 minutes]. During that time you will be using electronic health record software. I will ask you to complete a few tasks using this system and answer some questions. You should complete the tasks as quickly as possible, making as few errors as possible. Please try to complete the tasks on your own following the instructions very closely. Please note that we are not testing you; we are testing the system. Therefore, if you have difficulty all this means is that something needs to be improved in the system. I

will be here in case you need specific help, but I am not able to instruct you or provide help in how to use the application.

Overall, we are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. I did not have any involvement in its creation, so please be honest with your opinions. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time. Should you feel it necessary, you are able to withdraw at any time during the testing.

Following the procedural instructions, participants were shown the EHR and, as their first task, were given time (20] minutes) to explore the system and make comments. Once this task was completed, the administrator gave the following instructions:

For each task, I will read the description to you and say, "Begin." At that point, please perform the task and say, "Done," once you believe you have successfully completed the task. I would like to request that you not talk aloud or verbalize while you are performing the tasks. I will ask you your impressions about the task once you are done.

Participants were then given [7] tasks to complete. Tasks are listed in the moderator's guide in Appendix [B4].

3.9 USABILITY METRICS

According to the NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records, EHRs should support a process that provides a high level of usability for all users. The goal is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing.

The goals of the test were to assess:

1. Effectiveness of [eClinicalWorks] by measuring participant success rates and errors

2. Efficiency of [eClinicalWorks] by measuring the average task time and path deviations

3. Satisfaction with [eClinicalWorks] by measuring ease of use ratings

DATA SCORING

The following table (Table [1]) details how tasks were scored, errors evaluated, and the time data analyzed.

Measures, Rationale and Scoring:

Measures	Rationale and Scoring
Effectiveness: **Task Success**	A task was counted as a "Success" if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis. The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage. Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency. Optimal task performance time, as benchmarked by expert performance under realistic conditions, is recorded when constructing tasks. Target task times used for task times in the Moderator's Guide must be operationally defined by taking multiple measures of optimal performance and multiplying by some factor [10] that allows sometime buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was [30] seconds then allotted task time performance was [30 * 10 = 300 seconds]. This ratio should be aggregated across tasks and reported with mean and variance scores.
Effectiveness: **Task Failures**	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a "Failure." No task times were taken for errors. The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors. On a qualitative level, an enumeration of errors and error types should be collected. This should also be expressed as the mean number of failed tasks per participant
Efficiency: **Task Deviations**	The participant's path (*i.e.,* steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation. It is strongly recommended that task deviations be reported. Optimal paths (*i.e.,* procedural steps) should be recorded when constructing tasks.

Efficiency: Task Time	Each task was timed from when the administrator said, "Begin," until the participant said, "Done." If he or she failed to say "Done," the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.
Satisfaction: Task Rating	Each participant's subjective impression of the ease-of-use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate "Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). This data ware averaged across participants. Common convention is that average ratings for systems judged easy-to-use should be 3.3 or above. To measure participants' confidence in and likeability of [eClinicalWorks] overall, the testing team administered the System Usability Scale (SUS) post-test questionnaire. Questions included, "I think I would like to use this system frequently," "I thought the system was easy to use," and "I would imagine that most people would learn to use this system very quickly." See full System Usability Score questionnaire in Appendix 5.13

Table [1]. Details of how observed data were scored.

4 RESULTS

4.1 DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section, located above. Participants who failed to follow session and task instructions had their data excluded from the analysis.

The usability testing results for eClinicalWorks are detailed below (see Table [1]). The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance.

The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be: [4]. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

4.2 DISCUSSION OF THE FINDINGS

EFFECTIVENESS

The software has a lot to offer. The storage of the software is quite remarkable. I feel confident that I can complete work effectively in the software. Non users: If I had training or had more experience with software I can be more effective. Easy to use. The assessment tool is intuitive. A lot of visit information on the screen.

EFFICIENCY

If users properly use the software, it can be very effective. However, the multiple clicks can be a bit too much. If the clicks are brought down, one can be very efficient. The search features are great, as well as all the drop downs.

SATISFACTION

Users like the software; they expressed that it is easy to use once you understand and gain experience with the software. The storage of patient information is remarkable. However, the screens and views of the software are a bit cluttered with options and links. Also, the colors in the software are a bit overwhelming. On a whole all of the options offered are great, and cater to a lot of needs.

MAJOR FINDINGS

The software has a lot to offer. All the information you could possibly need is all around you in multiple screens, helping to quickly access information. There are multiple links to choose from, which is a bit overwhelming, but may be needed at certain times and in certain situations.

AREAS FOR IMPROVEMENT

Software clicks could be decreased. There is a lot of what seems to be over-clicking. There are a bit too many colors; it could have a cleaner, more consistent look with the colors; all of the colors are too much. There is a variance in the font size from screen to screen. Overwhelming features; there needs to be more clear navigation.

Quality Management System (QMS)

eClinicalWorks uses a proprietary, home-grown QMS during the development, testing, implementation and maintenance of the EHR software application.

Privacy &Security

170.314(d)(2): Security levels on the front end ensure that the access logs are only viewable and prevent users from editing them. Access logs are also encrypted on the database preventing users from accessing the logs. Previous access logs are never deleted when new logs are entered. Data elements in the access logs are reflected as a modified status to identify if any changes have been made to them. eClinicalWorks generates an encrypted key using SHA-1/SHA-2 with every log that is generated .The key is generated using elements within the log and an eCW security pass phrase. The encrypted key is stored in a separate table in the database. If a log was altered, the user can view the exception directly within the current tab, as it will be marked in red. In the instance if a log was deleted, the user can view deleted logs on the "Missing Logs" tab.

170.314(d)(7): Electronic Health Information is not stored on end-user devices.