DATE: 07/30/2019

COMPLETE SOFTWARE SOLUTIONS
FOR OFFICE, SURGERY CENTER
AND HOSPITAL

INFINITE SOFTWARE SOLUTIONS, INC.
d/b/a: MD-REPORTS
The Corporate Park of Staten Island
1110 South Avenue, Suite 303
Staten Island, NY 10314
Phone : (718) 982-1315
Fax : (718) 477-3692

Whether you have an Ambulatory Center, Surgery Center, Office group or Hospital, MD-Reports seamlessly interfaces with Pathology, Billing/PMS and HIS companies.

MD-Reports EHR Letter of Attestation for Test Criteria: 170.315.G.3: Safety Enhanced Design

Date: 07/30/2019

This letter is being submitted in attestation to the accuracy of the information contained in the following MD-Reports EHR Safety-Enhanced Design Usability Report. This report is being submitted as part of the EHR certification requirements outlined in 170.315(g)(3)- Safety Enhanced Design.

Regards,

Sarada Deepthi Madireddy
QA Manager

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Note: The following study was developed using the NISTIR 7742 template as a guide for reporting our findings: *Customized Common Industry Format Template for Electronic Health Record Usability Testing.*

Date of Usability Test: 7/10/2019
Date of Report: 7/18/2019
Version: MD-Reports EHR Version 10 (MU3)

Report Prepared by: MD-Reports Quality assurance team
                        Sarada Deepthi Madireddy,QA Manager

Location: 1110 South Avenue, Suite 303
                        Staten Island, NY 10314
                        Email: deepthi@md-reports.com
                        Phone: (718) 982-1315 ext. 127

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EXECUTIVE SUMMARY

A usability test of MD-Reports EHR Version 10 MU3 was conducted on 7/10/2019 in 1110 South Avenue, Staten Island NY 10314 by MD-Reports quality assurance team. 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, 10 healthcare providers matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

User-Centered Design Process

NIST 7742 was referenced for MD-Reports EHR's user-centered design process.
According to the National Institute of Standards and Technology (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 goals are for users to interact with the system safely, effectively, efficiently, and with an acceptable level of satisfaction. To this end, design to optimize for safety, effectiveness, efficiency and user satisfaction was utilized throughout the design and development cycle.
The following key principles of the NISTIR 7742 were followed:
- The design is based on the understanding of specific user group needs, workflows and environments.
- Users are involved throughout the design and development.
- The design is driven and refined by user-centered evaluation and feedback.
- The design addressed the whole user experience.
- The design is adapted with users until performance objectives are met.
- The process is iterative.
Reference: National Institute of Standards and Technology. (2010). NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records (NISTIR 7742). Gaithersburg, MD.
https://ws680.nist.gov/publication/get_pdf.cfm?pub_id=907312

This study collected performance data on 12 below tasks (divided into 14) typically conducted on an EHR:

- Computerized Provider Order Entry (CPOE) – medications

- CPOE – laboratory

- CPOE – diagnostic imaging

- Drug-drug, Drug-allergy Interaction Checks for CPOE

- Demographics

- Problem List

- Medication List

- Medication Allergy List

- Clinical Decision Support

- Implantable Device List

- Clinical Information Reconciliation and Incorporation

- Electronic Prescribing

During the first 60 minutes of 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 prior experience with the EHR. The administrator introduced the test, and instructed participants to complete a series of tasks (given one at a time) using the EHRUT. 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.

Reference:
National Institute of Standards and Technology. (2010). *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records* (NISTIR 7742). Gaithersburg, MD.
www.nist.gov/manuscript-publicationsearch.cfm?pub_id=907313.
http://ws680.nist.gov/publication/get_pdf.cfm?pub_id=907312

If training or help materials were provided, describe the nature of it. The recommendation is that all participants be given the opportunity to complete training similar to what a real end user would receive prior to participating in the usability test.

Participant screens 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 not compensated with for their time. Various recommended metrics, in accordance with the examples set forth in the (NISTIR 7741)NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records, were used to evaluate the usability of the EHRUT. Following is a summary of the performance and rating data collected on the EHRUT.

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

- Major findings

• Placing orders without the use of order sets take a few seconds longer, and the list of orderable test are vast. In electronic prescribing the use of the favorites list is indispensible for specialist; the list of prescriptions they prescribe is very limited in scope.
• Clinical decision support was not as intuitive. Requires more of a guide approach.
• Reconciliation of data from 2 sources also requires some improvements, and become more intuitive.

- Areas for improvement

• Creating decision support rules should be more of a step by step guided approach.

• Clinical decision support can be color coded so the end user will know what type of alert that is displaying. Medication, Allergies, and test results.

INTRODUCTION

The EHRUT tested for this study was MD-Reports EHR 10 MU3. Designed to present medical information to healthcare

Providers in ambulatory, outpatient setting, the EHRUT consists of encounter documentation (complaint, medications, allergies, medical history, problems list, assessment, plan), electronic prescription, scanning of external documents, internal messaging for providers and staff, and messages from patient to providers from patient portal. 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 the EHR Under Test (EHRUT). To this end, measures of effectiveness, efficiency and user satisfaction, such as placing medications orders, refills, allergy entry and review for drug to allergy alerts were captured during the usability testing.

METHOD

Participants

A total of 12 participants were tested on the EHRUT(s). Participants in the test were 2 Provider, and 1 Practice Manager. Participants were recruited by Infinite Software Solutions D\B\A MD-Reports and were compensated with one year of free support for their existing MD-Reports product for their time. In addition, participants had no direct connection to the development of or organization producing the EHRUT(s). 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.

Twelve participants (matching the demographics in the section on Participants) were recruited and twelve participated in the usability test. Zero participants failed to show for the study.

Participants were scheduled for 10 minute sessions with 2-3 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, and included each participant's demographic characteristics as provided by the recruiting firm

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 one EHR. 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.

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:

1.   Place a medication order, laboratory
2.   Electronically prescribe a medication
3.   Review drug-drug, and drug-allergy interaction
4.   Record a patient's medications list
5.   Correct the dosage of an exist medication patient is taking
6.   Record a new allergy,
7.   Add reaction to the allergy
8.   Enable clinical decision support
9.   Review a triggered decision support rule
10.   View diagnostic reference information
11.   View clinical information from 2 sources (medications list form 2 providers)
12.   Reconcile the medication from the 2 sources
13.   Review and save the reconciled medications
14.   Add Implantable Device

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.

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.

Each participant reviewed and signed an informed consent and release form (See Appendix 3). A representative from the test team witnessed the participant's signature.

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 experienced usability practitioners with 10+ years experience.

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 making as few errors and deviations as possible.

 Constructing appropriate tasks is of critical importance to the validity of a usability test. These are the actual functions, but most tasks contain larger and more fleshed out context that aligns with the sample data sets available in the tested EHR. Please consult usability references for guidance on how to construct appropriate tasks.

All participant data must be de-identified and kept confidential.

• 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, 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 indicating that they had received the compensation.

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.

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.

Test Environment

The EHRUT would be typically be used in a healthcare office or facility.

In this instance, the testing was conducted in MD-Reports office suite. For testing, the computer used a Dell Desktop running Windows 10

The participants used a keyboard, and mouse, along with the computer monitor when interacting with the EHRUT.

The MD-Reports EHR 10 MU3 used a BenQ 19" monitor with a screen resolution of 1280x1024 The application was set up by the MD-Reports implementation team according to the vendor's documentation describing the system set-up and preparation. The application itself was running on a

Windows, Microsoft .Net platform using a stage MU3 test database on a 10/1000 gigabit network 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).

Test Forms and Tools

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

1. Informed Consent

2. Moderator's Guide
3. Post-test Questionnaire

Examples of these documents can be found in Appendices 1-3 respectively. The Moderator's Guide was devised so as to be able to capture required data.

The participant's interaction with the EHRUT was captured and recorded digitally with screen capture software running on the test machine. Verbal comments were recorded with a microphone. The test session were captured and sent to another computer where the data logger observed the test session.

Participant Instructions

The administrator reads the following instructions aloud to the each participant :

Thank you for participating in this study. Your input is very important. Our session today will last about 80 minutes. During that time you will use an instance of an electronic health record.

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, s please be honest with your opinions. All of the information there are a variety of tools that record screens and transmit those recordings across a local area network for remote observations.

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 (5 minutes) to explore the system and make comments. Once this task was complete, 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 doing the tasks. I will ask you your impressions about the task once you are done.

Participants were then given 14 tasks to complete.

Usability Metrics

According to the (NISTIR 7741) 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 MD-Reports EHR 10 MU3 by measuring participant success rates and errors
2. Efficiency of MD-Reports EHR 10 MU3 by measuring the average task time and path deviations
3. Satisfaction with MD-Reports EHR 10 MU3 by measuring ease of use ratings

 Participants should not use a think-aloud protocol during the testing. Excessive verbalization or attempts to converse with the moderator during task performance should be strongly discouraged. Participants will naturally provide commentary, but they should do so, ideally, after the testing. Some verbal commentary may be acceptable between tasks, but again should be minimized by the moderator.

Data Scoring

The following table (Table [x]) details how tasks were scored, errors evaluated, and the time data analyzed.[10]

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 1.5 that allows some time buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was 15 seconds then allotted task time performance was 15 x 1.5 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 an "Failures." 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. This should also be expressed as the mean number of failed tasks per participant. On a qualitative level, an enumeration of errors and error types should be collected.
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.

An excellent resource is Tullis, T. & Albert, W. (2008). Measuring the User Experience. Burlington, MA: Morgan Kaufman. Also see www.measuringusability.com

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Errors have to be operationally defined by the test team prior to testing.

	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	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). These data are 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 the MD-Reports EHR 10 MU3 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.

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

RESULTS

Data Analysis and Reporting

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

See Tedesco and Tullis (2006) for a comparison of post-task ratings for usability tests. Tedesco, D. & Tullis, T. (2006) A comparison of methods for eliciting post-task subjective ratings in usability testing. *Usability Professionals association Conference*, June 12 – 16, Broomfield, CO.

The SUS survey yields a single number that represents a composite measure of the overall perceived usability of the system. SUS scores have a range of 0 to 100 and the score is a relative benchmark that is used against other iterations of the system.

Meaningful Use Criteria and Task	N #	Task Success	Path Deviation Total **Observed /Optimal**	Path Deviation Average **Observed/ Optimal**	Task Time (in Seconds) **Mean** (SD)	Errors **Mean** (SD)	Task Efficiency (5=Easy) **Mean** (SD)
170 315(a)(7) Medication List Record the patient medication	12	12	26/24	4.33/4.0	23.5 (9.64)	.17 (.40)	4.5 (.54)
170 315(a)(7) Medication List Access and change the patient medication	12	12	25/24	4.16/4.0	25.8 (17.33)	0 (0)	4.3 (.75)
170 315(a)(8) Medication allergy List Record patient allergies/med allergies	12	9	52/48	8.66/8	21.3 (6.41)	.83 (.75)	4.1 (.75)
170 315(a)(8) Medication allergy List Access and update patient allergies/med allergies	12	12	28/24	4.66/4.0	12.5 (6.94)	.67 (.81)	4.6 (.51)
170 315(b)(2) Clinical Information Reconciliation Reconcile clinical information	12	10	28/24	4.66/4.0	55.8 (58.91)	.67 (.75)	4.5 (.51)
170.315(a)(3) CPOE Record Radiology Order	12	11	26/24	4.33/4.0	27.6 (18.17)	.17 (.40)	4.5 (.54)
170.315(a)(3) CPOE Access/Change Radiology Order	12	11	31/30	5.16/4.0	18 (10.46)	.17 (.40)	4 (.63)
170.315(a)(2) CPOE Record Lab Order	12	12	30/24	5.0/4.0	20.8 (12.70)	.33 (.51)	4.3 (.51)
170.315(a)(2) CPOE Access/Change Lab Order	12	12	25/24	4.16/4.0	15.5 (6.80)	0 (0)	4 (.63)
170 315(a)(9) Clinical Decision Support Review/Configure Clinical Decision Support and Therapeutic References	12	12	31/30	5.16/4.0	19.8 (7.22)	.17 (0)	4.3 (.51)
170.315(a)(4) Drug-drug, Drug-allergy interaction checks Record Medication Order/Review Drug-Drug, Drug- Allergy interaction check	12	12	47/42	7.83/7.0	45 (11.00)	.17 (.40)	4 (.63)
170.315(a)(1) CPOE Access and Change Medication Order	12	12	24/24	4.0/.4.0	21.8 (7.60)	0 (0)	4 (.63)
170 315(b)(3) Electronic Prescribing	12	12	30/30	5.0/5.0	15 (2.94)	0 (0)	3.8 (.75)
170.315(a)(6) Record and change problem	12	12	32/30	5.33/5.0	22 (10.86)	.17 (.40)	4.8 (.40)
170.315(a)(5) Record Demographics for Race, Ethnicity, Language, Sexual Orientation, Gender Identity	12	12	30/30	5.0/5.0	15 (2.94)	0 (0)	4.5 (.54)
170.315(a)(14) Record Implant Device Change Status, Access UDI info	12	12	30/30	4.0/4.0	21.8 (7.60)	0 (0)	4.5 (.54)

The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be: 86.5. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.[15]

Discussions of Findings

Note that this table is an example. You will need to adapt it to report the actual data collected.

Creating clinical support decision rules and reconciling medications from 2 or more sources need some improvements; should support a more step by step or guided approach. The current solution looks to be implemented with some with a higher understanding of how rules are created, by advanced users or system administrators.

EFFECTIVENESS: Clinical provider order entry seems very well received and, as well as electronic prescribing. Recording of allergies, and medications also seem to very intuitive. Creating clinical support triggers, as well as reconciling medications from multiple sources seem to be areas the usability looks like it's geared for advanced users.

EFFICIENCY: Most of the provider centered task seems very much easy, or obvious task that can be completed successfully without deviation. When it comes to create rules and reconciling data it seems the usability can be confusing from the steps to complete the task.

SATISFACTION: Overall satisfaction by the end user seems to be good. The task performed with documenting, medications, allergies, placing orders were all very intuitive and performed easily. Task requiring the creating of rules, and clinical decision support were less intuitive, and require design changes to make the process more of a guide step, with more prompts and notes.

Major Findings

- Placing orders without the use of order sets take a few seconds longer, and the list of orderable test are vast. In electronic prescribing the use of the favorites list is indispensible for specialist; the list of prescriptions they prescribe is very limited in scope.
- Clinical decision support was not as intuitive. Requires more of a guide approach.
- Reconciliation of data from 2 sources also requires some improvements, and become more intuitive.

Areas of Improvements

- Creating decision support rules should be more of a step by step guided approach.

- Clinical decision support can be color coded so the end user will know what type of alert that is displaying. Medication, Allergies, and test results

APPENDICES

The following appendices include supplemental data for this usability test report. Following is a list of the appendices provided:

1: Participant demographics

2: Example Moderator's Guide

3: System Usability Scale Questionnaire

The report should contain a breakdown of the key participant demographics. A representative list is shown below.

Following is a high-level overview of the participants in this study.

	Part ID	Gender	Age	Education	Occupation/ role	Professional Experience (Months)	Computer Experience (Months)	Product Experience (Months)	Assistive Technology Needs
1	101	Male	40-49	MD	MD, GI	246	348	60	No
2	102	Female	40-49	BSA	RN	126	330	24	No
3	103	Male	40-49	MD	RN	182	348	36	No
4	104	Female	40-49	BSA	RN	168	340	24	No
5	105	Female	30-39	BSA	RN	120	180	12	No
6	106	Female	40-49	BSA	PA	230	350	36	No
7	107	Male	40-49	BSA	PA	122	350	60	No
8	108	Female	40-49	RN	MA	156	348	48	No
9	109	Male	40-49	RN	MA	144	330	24	No
10	110	Female	40-49	RN	MA	168	335	36	No
11	111	Female	40-49	BSA	RN	180	355	60	No
12	112	Female	30-39	BSA	RN	96	190	24	No

Informed Consent

Infinite Software Solutions would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health records system. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about *60* minutes.

Agreement

I understand and agree that as a voluntary participant in the present study conducted by *Infinite Software Solutions I* am free to withdraw consent or discontinue participation at any time.

I understand and agree that the purpose of this study is to make software applications more useful and usable in the future.

I understand and agree that the data collected from this study may be shared with outside of *Infinite Software Solutions* and *their* client(s). I understand and agree that data confidentiality is assured, because only de- identified data – i.e., identification numbers not names – will be used in analysis and reporting of the results.

I agree to immediately raise any concerns or areas of discomfort with the study administrator. I understand that I can leave at any time.

Please check one of the following:

☐ YES, I have read the above statement and agree to be a participant.

☐ NO, I choose not to participate in this study.

Signature:

Date: 7/10/2018

Informed Consent

Infinite Software Solutions would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health records system. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about *60* minutes.

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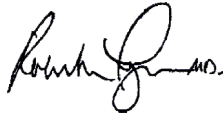
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I agree to immediately raise any concerns or areas of discomfort with the study administrator. I understand that I can leave at any time.

Please check one of the following:

☐   YES, I have read the above statement and agree to be a participant.

☐   NO, I choose not to participate in this study.

Signature:

Date: 7/10/2018

Appendix 2: Example Moderator's Guide

Only three tasks are presented here for illustration.

Moderator's Guide

Administrator Jane Widlund

Data Logger Sarada Deepthi Madireddy

Date 7/10/2019   **Time** 2:00pm

Location 1110 South Avenue, Suite 303 Staten Island NY 10314

<u>Prior to testing</u>
- ☐ Confirm schedule with Participants
- ☐ Ensure EHRUT lab environment is running properly
- ☐ Ensure lab and data recording equipment is running properly

<u>Prior to each participant:</u>
- ☐ Reset application
- ☐ Start session recordings with *tool*

<u>Prior to each task:</u>
- ☐ Reset application to starting point for next task

<u>After each participant:</u>
- ☐ End session recordings with *tool*

<u>After all testing</u>
- ☐ Back up all video and data files

Orientation (10 minutes)

Thank you for participating in this study. Our session today will last 60 **minutes**. During that time you will take a look at an electronic health record system.

I will ask you to complete a few tasks using this system and answer some questions. 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. You will be asked to complete these tasks on your own trying to do them as quickly as possible with the fewest possible errors or deviations. Do not do anything more than asked. If you get lost or have difficulty I cannot answer help you with anything to do with the system itself. Please save your detailed comments until the end of a task or the end of the session as a whole when we can discuss freely.

I did not have any involvement in its creation, so please be honest with your opinions.

The product you will be using today is *describe the state of the application, i.e., production version, early prototype, etc*. Some of the data may not make sense as it is placeholder data.

We are recording the audio and screenshots of our session today. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time.

Do you have any questions or concerns?

Preliminary Questions (*5* minutes) Dr. Lazar

What is your job title / appointment? MD

I work as an MD in my privately owned practice

How long have you been working in this role? For the Past

15 years

What are some of your main responsibilities?

I see patients for digestive disorders; Screening, diagnostic,

and preventative care. I perform procedures on some of the

patients that I see.

Tell me about your experience with electronic health records.
I have been using an EMR for the past 5 years, and have had no major complaints. The first year was a transition period, some electronic, and some paper.

Preliminary Questions (*5* minutes)   **Kathy**

What is your job title / appointment? Practice Manager

I work as an office manager in a privately owned practice

How long have you been working in this role? For the Past

15 years, since the doctor opened the office.

What are some of your main responsibilities?

Triage patients, check patients insurance/eligibility, take

their Vitals if no MA is available. I sometimes handle refills

for the Doctor.

Tell me about your experience with electronic health records.
I have been using an EMR for the past 5 years, and have been there day one of implementing MD-Reports. We gradually transitioned from paper to 95% electronic.

Task 1: CPOE (Enter order)

Take the participant to the starting point for the task.

Enter test/lab order.

Success:

- ☐ Easily completed
- ☐ Completed with difficulty or help :: Describe below
- ☐ Not completed

Comments:

Task Time: ___7___ Seconds

Optimal Path: *Plan Screen ☐ Click on Lab/Test Orders ☐ Click Add button ☐ Click Test Type dropdown and choose a test ☐ Click Test Order Date field and type in Test Date ☐ Click Add to Report button*

- ☐ Correct
- ☐ Minor Deviations / Cycles :: Describe below
- ☐ Major Deviations :: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _1_____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 2: Electronically prescribe a medication

Take the participant to the starting point for the task.

Prescribe medication Lipitor.

Note that patient already has a previously selected Pharmacy.

Success:

- ☐ Easily completed
- ☐ Completed with difficulty or help :: Describe below
- ☐ Not completed

Comments:

Task Time: _____20_____ Seconds

Optimal Path: *Plan Screen ☐ Click on Prescription ☐ Type in 'LIPITOR' drug to search ☐ Click Drug Search button ☐ Choose drug from the list ☐ Select Frequency from list ☐ Choose Days Supply ☐ Choose number of refills ☐ Click Save Rx button ☐ Click Take Complete Rx to Review page ☐ Click Transmit Rx ☐ Click Transmit Rx/ Add to Record*

- ☐ Correct
- ☐ Minor Deviations / Cycles :: Describe below
- ☐ Major Deviations :: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: 1

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 3: Review drug-drug drug-allergy interaction

Take the participant to the starting point for the task. Ensure that this patient has a drug-drug and a drug-food allergy to the drug chosen. This will put force the participant to find other drugs and use other elements of the application.

After examining *Patient,* you have decided to put this patient on a Simvastatin after prescribing Cardizem. Check for any interactions and place an order for this medication.

For drug-allergy interaction, patient is allergic to penicillin. Prescribe Amoxicillin to patient to check interaction.

Success:

    ☐   Easily completed
    ☐   Completed with difficulty or help :: Describe below
    ☐   Not completed
    Comments:

Task Time: ___1___ Seconds

Optimal Path:

Drug-drug Interaction:

Plan Screen ☐ Click on Prescription ☐ Type in 'CARDIZEM' letters of drug to search ☐ Click Drug Search button ☐ Choose Cardizem from the list ☐ Select Frequency from list ☐ Choose Days Supply ☐ Choose number of refills ☐ Click Save Rx button

Type in 'SIMVASTATIN' letters of drug to search ☐ Click Drug Search button ☐ Choose SIMVASTATIN from the list ☐ A message will display warning about the interaction☐

Drug-allergy Interaction: Note that patient is allergic to penicillin.
Plan Screen ☐ Type in 'AMOXICILLIN' letters of drug to search ☐ Click Drug Search button ☐ Choose AMOXICILLIN from the list ☐ A message will display warning about the interaction

    ☐   Correct
    ☐   Minor Deviations / Cycles :: Describe below
    ☐   Major Deviations :: Describe below
    Comments:

Observed Errors and Verbalizations:
Comments:

Rating:

    Overall, this task was: _1_

    Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 4: Medication, record a new medication

Take the participant to the starting point for the task.

Record new medication. After examining *Patient,* you have decided to put this patient on LIPITOR.

Success:

- ☐ Easily completed
- ☐ Completed with difficulty or help :: Describe below
- ☐ Not completed

Comments:

Task Time: ___9___ Seconds

Optimal Path: *Medications/Allergies Screen ☐ Click on Meds/Allergies/E-Rx button ☐ Type 'LIPITOR' in drug to search ☐ Click Drug Search button ☐ Choose 'LIPITOR 40 mg' from the list ☐ Click Select to Move to Current Meds button*

- ☐ Correct
- ☐ Minor Deviations / Cycles :: Describe below
- ☐ Major Deviations :: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _1_____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 5: Medication, change an existing medication

Take the participant to the starting point for the task.

Change existing medication. Patient is on 20 mg Lipitor. Change dosage to 40 mg.

Success:

      ☐ Easily completed
      ☐ Completed with difficulty or help :: Describe below
      ☐ Not completed
      Comments:

Task Time: _____5_____ Seconds

Optimal Path: *Medications/Allergies Screen ☐ Click on Meds/Allergies/E-Rx button ☐ Under Current Meds section, click EDIT button for Lipitor ☐ Make changes to existing medication ☐ Click Save Rx button*

      ☐ Correct
      ☐ Minor Deviations / Cycles :: Describe below
      ☐ Major Deviations :: Describe below
      Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

      Overall, this task was: _1_____

      Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 6: Medication allergy, record a new allergy

Take the participant to the starting point for the task.

Record new allergy. Patient is allergic to Penicillin.

Success:

- ☐ Easily completed
- ☐ Completed with difficulty or help :: Describe below
- ☐ Not completed

Comments:

Task Time: ___4___ Seconds

Optimal Path: *Medications/Allergies Screen☐ Click on Meds/Allergies/E-Rx button ☐ Click Allergy/Intolerance button ☐ Click on the list of Common Allergies, Penicillins ☐ Click Severity dropdown and choose 'Moderate' severity ☐ Click On Set Date (when applicable) ☐ Click Save Allergy button*

- ☐ Correct
- ☐ Minor Deviations / Cycles :: Describe below
- ☐ Major Deviations :: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _1_____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 7: Medication allergy, change an existing allergy

Take the participant to the starting point for the task.

Change allergy. Patient is allergic to Penicillin. Change allergy severity to Low.

Success:

 ☐ Easily completed
 ☐ Completed with difficulty or help :: Describe below
 ☐ Not completed
 Comments:

Task Time: ___4___ Seconds

Optimal Path: *Medications/Allergies Screen☐ Click on Meds/Allergies/E-Rx button ☐ Under Allergy List click Penicillins☐ Click Severity dropdown to change severity to LOW☐ Click On Set Date to change on set date☐ Click Save Allergy button*

 ☐ Correct
 ☐ Minor Deviations / Cycles :: Describe below
 ☐ Major Deviations :: Describe below
 Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

 Overall, this task was: _1_____

 Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 8: CDS, enable intervention support

Take the participant to the starting point for the task.

Create Clinical Data Support intervention for '*Mammogram for women over 40 yrs of age*'.

Success:

- ☐ Easily completed
- ☐ Completed with difficulty or help :: Describe below
- ☐ Not completed

Comments:

Task Time: _____6_____ Seconds

Optimal Path: *Main Screen ☐ Click Tools & Settings ☐ Choose Patient Alert Rules ☐ Click Create New button ☐ Choose General Rule ☐ Type 'Mammogram for women over 40 yrs of age' in Title field ☐ Choose 1 Day for Frequency ☐ Click Save button ☐*

Add/Edit Patient Rule tab ☐ Click Module dropdown ☐ Choose Demographics ☐ Click Criteria dropdown ☐ Choose Gender ☐ Click Operator dropdown ☐ Choose = ☐ Click Gender dropdown ☐ Choose Female ☐ Click Combinatory Operator ☐ Choose AND ☐ Click ADD button ☐ Click Module dropdown ☐ Choose Demographics ☐ Click Criteria dropdown ☐ Choose Age ☐ Click Operator dropdown ☐ Choose >= ☐ Type '40' in Value field ☐ Click Combinatory Operator ☐ Choose END ☐ Click ADD button ☐ Click SAVE button

Patient Rule Action tab ☐ Click ADD button ☐ Type 'Schedule patient for mammogram' in Action/Description text box ☐ Click SAVE button

Permitted User Roles tab ☐ Select users who will see the alert ☐ Click SAVE button

- ☐ Correct
- ☐ Minor Deviations / Cycles :: Describe below
- ☐ Major Deviations :: Describe below

Comments:

Observed Errors and Verbalizations:

Comments: Was not clear the save the name of the alert first, before adding the alert trigger

Rating:

Overall, this task was: _4

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 9: CDS, review a triggered decision

Take the participant to the starting point for the task.

CDS saved for *Mammogram for women over 40 yrs of age'.*

Success:

- ☐ Easily completed
- ☐ Completed with difficulty or help :: Describe below
- ☐ Not completed

Comments:

Task Time: ____5____ Seconds

Optimal Path: *Patient Details Screen* ☐ *Search for female patient over 40 yrs of age* ☐ *Alert button will flash*

- ☐ Correct
- ☐ Minor Deviations / Cycles :: Describe below
- ☐ Major Deviations :: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _1_____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 10: CDS, view diagnostic reference information

Take the participant to the starting point for the task.

Patient education information referenced in Clinical Decision Support.

Success:

□ Easily completed
□ Completed with difficulty or help :: Describe below
□ Not completed
Comments:

Task Time: 5   Seconds

Optimal Path: *Alert Screen* □

□ Correct
□ Minor Deviations / Cycles :: Describe below
□ Major Deviations :: Describe below
Comments:

Observed Errors and Verbalizations:
Comments:

Rating:

Overall, this task was: _1_____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 11: Clinical information reconciliation, view data from at least 2 sources

Take the participant to the starting point for the task.

View Medication Reconciliation information from 2 sources.

Success:

☐ Easily completed
☐ Completed with difficulty or help :: Describe below
☐ Not completed
Comments:

Task Time: ____5____ Seconds

Optimal Path: *Main Screen ☐ Click on Reports menu ☐ Choose Medication Reconciliation option   ☐ Type Patient ID in patient ID field ☐ Medications are displayed in the grid*

☐ Correct
☐ Minor Deviations / Cycles :: Describe below
☐ Major Deviations :: Describe below
Comments:

Observed Errors and Verbalizations:
Comments:

Rating:

Overall, this task was: 1_____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 12: Clinical information reconciliation, merge data from 2 or more sources

Take the participant to the starting point for the task.

Merge medications from 2 different sources.

Success:

- ☐ Easily completed
- ☐ Completed with difficulty or help :: Describe below
- ☐ Not completed

Comments:

Task Time: _____5_____ Seconds

Optimal Path: *Main Screen ☐ Click on Reports menu ☐ Choose Medication Reconciliation option ☐ Type Patient ID in patient ID field ☐ Click on check boxes of medications to be merged ☐ Click ADD TO RECONCILED MEDICATIONS button ☐*

- ☐ Correct
- ☐ Minor Deviations / Cycles :: Describe below
- ☐ Major Deviations :: Describe below

Comments:

Observed Errors and Verbalizations:

Comments: Was not as clear on which side patient ID needed to be selected with checkbox

Rating:

Overall, this task was: ‾

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 13: Clinical information reconciliation, review and saved

Take the participant to the starting point for the task.

Review and save clinical information reconciliation.

Success:

- ☐ Easily completed
- ☐ Completed with difficulty or help :: Describe below
- ☐ Not completed

Comments:

Task Time: ____4____ Seconds

Optimal Path: *Main Screen ☐ Click on Reports menu ☐ Choose Medication Reconciliation option ☐ Type Patient ID in patient ID field ☐ Click on check boxes of medications to be merged ☐ Click ADD TO RECONCILED MEDICATIONS button ☐ Click SAVE button*

- ☐ Correct
- ☐ Minor Deviations / Cycles :: Describe below
- ☐ Major Deviations :: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: 1_____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 14: Implantable Device

Take the participant to the starting point for the task.
Record the ID # (01)10884521062856(11)141231(17)150707(10)A213B1(21)1234.
Click on the Implant to reveal device description, identifiers, and attributes
Review and save clinical information reconciliation.

Success:

☐ Easily completed
☐ Completed with difficulty or help :: Describe below
☐ Not completed
Comments:

Task Time: ___4___ Seconds

Optimal Path: *Main Screen ☐ Click on Reports menu ☐ Choose Consultation Tab ☐ Type Patient ID in patient ID field ☐ Click on Implantable Devises ☐ Click ADD Implantable button ☐ Click SAVE button*

☐ Correct
☐ Minor Deviations / Cycles :: Describe below
☐ Major Deviations :: Describe below
Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: 1_____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

What was your overall impression of this system? What aspects

of the system did you like most? What aspects of the system did

you like least?

Were there any features that you were surprised to see?

What features did you expect to encounter but did not see? That is, is there anything that is missing in this application?

Compare this system to other systems you have used. Would you

recommend this system to your colleagues? *Administer the SUS*

In 1996, Brooke published a "low-cost usability scale that can be used for global assessments of systems usability" known as the System Usability Scale or SUS. Lewis and Sauro (2009)   and others have elaborated on the SUS over the years. Computation of the SUS score can be found in Brooke's paper, in at http://www.usabilitynet.org/trump/documents/Suschapt.doc *or in Tullis and Albert (2008).*

Appendix 3: System Usability Scale
Questionnaire

Strongly   Strongly disagree
agree

1	2	3	4	5

1. I think that I would like to use this system frequently

1	2	3	4	5

2. I found the system unnecessarily complex

1	2	3	4	5

3. I thought the system was easy to use

1	2	3	4	5

4. I think that I would need the support of a technical person to be able to use this system

1	2	3	4	5

5. I found the various functions in this system were well integrated

1	2	3	4	5

6. I thought there was too much inconsistency in this system

1	2	3	4	5

7. I would imagine that most people would learn to use this system very quickly

1	2	3	4	5

8. I found the system very cumbersome to use

1	2	3	4	5

9. I felt very confident using the system

1	2	3	4	5

10. I needed to learn a lot of things before I could get going with this system

1	2	3	4	5

[16] Brooke, J.: SUS: A "quick and dirty" usability scale. In: Jordan, P. W., Thomas, B., Weerdmeester, B. A., McClelland (eds.) *Usability Evaluation in Industry* pp. 189--194. Taylor & Francis, London, UK (1996). SUS is copyrighted to Digital Equipment Corporation, 1986.

Lewis, J R & Sauro, J. (2009) "The Factor Structure Of The System Usability Scale." in *Proceedings of the Human Computer Interaction International Conference (HCII 2009), San Diego CA, USA*