iCare

iCare.com Electronic Health Record Usability Testing Report

Safety Enhanced Design Study
iCare.com, Inc.
iCare EHR Version 2

EHR Usability Test Report of iCare version 2

This report is based on ISO/IEC 25062:2006 Common Industry Format for Usability Test Reports

iCare.com Electronic Health Record, Version 2

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Executive Summary

Members of the iCare Product Management team conducted a usability test of the iCare Electronic Health Record (EHR), version 2, on 12/10/2019 and 12/16, 2019 in the iCare Development Center. The purpose of this test was to test and validate the usability of the current user interface and to provide evidence of the safety enhanced design of the EHR Under Test (EHRUT).

The iCare EHR has been designed for inpatient and ambulatory clinical documentation, computerized order entry, and clinical decision-making in medical facilities. This product is also being utilized in academic environments as a tool for students preparing for careers in nursing and health information technology. The test cohort included at least one physician, nurse, pharmacist, health information technician, lab technician, and billing and financial specialist.

The test collected performance data on various tasks required by the Office of the National Coordinator (ONC) for a Meaningful Use certified EHR. The areas included in this study were:

1. 170.315 a.1 CPOE Medication
2. 170.315 a.2 CPOE Laboratory
3. 170.315 a.3 CPOE Diagnostic Imaging
4. 170.315 a.4 Drug-drug, Drug-Allergy Interactions Checks
5. 170.315 a.5 Demographics
6. 170.315 a.6 Problem List
7. 170.315 a.7 Medication List
8. 170.315 a.8 Medication Allergy List
9. 170.315 a.9 Clinical Decision Support
10. 170.315 a.14 Implantable Devices
11. 170.315 b.2 Clinical Information Reconciliation

Each test participant was selected as new users with little or no formal training on the use of the iCare EHR. Each participant was given an introductory session covering basic navigation prior to beginning the test.

The following types of data were collected for each participant:

- Number of tasks successful completed within allotted time without assistance.
- Time to complete the tasks

- Number and types of errors
- Path deviations
- Participants verbalizations
- Participants satisfaction ratings of the system

The usability tests were conducted as baseline tests for end-user computer competency and an introduction to the product without formal training. The test administrator did not provide assistance to the participants in how to complete the tasks. Each test lasted approximately two hours with a three-hour time limit.

All participant data was de-identified so that no correlation could be made between the participants and the test results. Following the end of the test period a verbal discussion was conducted to gather general comments and feedback about the iCare product.

The overall results and feedback gathered from the test, determined that the iCare EHR has been designed with enough flexibility to support various types of end-user workflows while maintaining the integrity of the data being entered or presented for clinical decision making. As functionality is modified or increased based on future input from end-users the design foundation should not hinder the usability of the application.

Major Findings:

- The design of the user screens remains consistent throughout the application which supports users to quickly gain a level of proficiency navigating through the system.

- Sections of the application are clearly labeled and navigation is straightforward.

- Menus within the sections/screens of the application apply to the functionality the section is designed to support.

- In areas important to patient safety, information warnings appear that provide the user with data needed for decision-making, however the application does not force a workflow or decision on the user.

- A comparison of menu options available to the end user is based on the permissions of the user profiles assigned to the user.

- Users reported high satisfaction.

Areas for Improvement:

- Several configuration options caused confusion by some users. For example, the setting for e-signatures caused several users to add additional steps when changing orders.

- On Apple computers running Mac OS, several users were confused by scrolling direction and the auto-hiding scroll bars.

Introduction

The EHRUT tested for this study was the iCare Electronic Health Record, version 2, for complete inpatient functionality as required by the Office of the National Coordinator (ONC) for Meaningful Use certification.

Designed to present medical information to healthcare providers and health information technicians in hospitals and academic settings, the EHRUT consists of a cloud based design that supports real-time data capture and presentation within a secured user interface for documenting and retrieving patient data valuable for clinical decision making and supporting actions required for patient care. 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 to provide evidence of safety enhanced design in the EHR Under Test (EHRUT). To this end, measures of effectiveness, efficiency and user satisfaction, such as clicks, time on task, errors and success rate, were captured during the usability testing.

User Centred Design

The staff at iCare.com continues to focus on the human-centered design approach for the iCare Electronic Health Record (EHR). By focusing on the users, their needs and requirements, and incorporating required patient safety measures we follow the principles of the ISO standard 9241-210:2010.

At iCare, we consider our design process as a collaborative effort that includes input from our users, as well as other industry subject matter experts, to research, create, test, and release functionality that is client-centered, function driven, and supports patient safety. User

requirements are continuously obtained, reviewed, and utilized from the beginning of the design of functionality within the product, whether it is new functionality under consideration or current functionality that is to be modified based on user feedback, until the final release process.

The input obtained from users throughout the research, design, and testing processes is what drives our efforts. The process begins with an idea or a request - we then meet with users that specialize in the area that the functionality is being designed to support. We ask questions and take statements focused on goals, workflow, challenges, and measures for success. Following this type of design process helps ensure that the functionality will meet the needs of our users – current and future. We strive to have a product that maintains a consistent design that makes it easy for the user to navigate through the system with a minimum of effort. This consistency of the design supports our goal to have a product that has a reduced learning curve - each area in the product follows a similar format, for instance menu placement, once the user becomes familiar with how to initiate a command or access data in one section of the product, a similar action can be duplicated in another.

The basic design fundamentals that we adhere to ensures that the iCare EHR is a product that is accessible, consistent, effective, efficient, and meets its goals based on our user's duty-motivated needs.

Intended Users

The iCare system has been designed as a complete EHR for use in inpatient and ambulatory medical care facilities and as a tool for teaching future health care professionals.   The iCare EHR is currently being marketed to and used by nurses, doctors, and health information technicians as well as instructors in academic environments teaching students that are studying to enter these professions.

Test Method

Participants
A total of ten participants were tested on the EHRUT. There was a mixture of backgrounds and basic characteristic to provide a high-level cross-section of potential user backgrounds.

Participants were recruited by a combination of invitations and requests to new customers and applicants for open positions at the company as part of their computer use competency screening prior to the interview phase of the hiring process.

Participants were given the opportunity to have a basic orientation and introductory level of training as the actual end users would have received. Participants were told this testing was to provide a baseline of each user's knowledge of EHR navigation and that their scores and feedback would be used as usability and improvement data.

Below is a table of participants that includes demographics, professional experience, and computing experience. Participant names were replaced with User IDs so that the individual's data could not be connected to their identities.

USER ID	GENDER	AGE	EDUCATION	OCCUPATION/ROLE	PROFESSIONAL EXPERIENCE	COMPUTER EXPERIENCE	PRODUCT EXPERIENCE
01	Male	70-79	Master's	Chief Financial Officer	372	Expert	Some
02	Female	50-59	Associate	Nurse	120	Average	Oriented
03	Female	40-49	Some college	Health Information Manager	252	Average	None
04	Male	50-59	Some college	Lab Technician	180	Good	None
05	Male	50-59	Some college	Lab Technician	264	Good	None
06	Male	50-59	Doctorate	Pharmacy Manager	156	Good	None
07	Female	60-69	Associate	Medical Billing Specialist	60	Expert	None
08	Female	30-39	Bachelor's	Nurse	84	Average	None
09	Female	60-69	Bachelor's	Medical Billing Specialist	60	Average	None
10	Male	30-39	Doctorate	Physician	192	Good	Some

NOTE:

Participants were scheduled from fifteen to thirty minutes per functionality section with five to ten minute breaks between each area section test.

Test Design

The objective of this test was to uncover areas where the application performed as expected as well as areas where the application failed to meet the needs of the participants. The data from this test will serve as a baseline for future tests and updated versions of this application. The feedback from participants will be included with other suggestions for new or improved functionality for the product.

During the test, participants were encouraged to interact with each other in order for the facilitators to gage the type of spontaneous feedback would occur among users. The application was evaluated for effectiveness, efficiency and satisfaction as defined by the goal of each task to be completed. Overall, the participants did not report any deviation in understanding the objective or ability to complete the task within the time allotted.

Tasks

The tasks selected were determined on the needs of usability, user risk, and the ability to report findings for Meaningful Use reporting. The following areas were prioritized as follows for testing:

1. Record and Change a Medication Order
2. Record and Change a Laboratory Order
3. Record and Change a Imaging Order
4. Record and Change Patient Demographics
5. Record and Change Problem List
6. Record and Change Medication List
7. Record and Change Medication Allergy List
8. Trigger a drug-drug interaction and drug-allergy alert by entering a new medication order
9. Add, Trigger, and View CDS Interventions.
10. Record Change Implantable Devices list with UDI

11. Incorporate CCDA and conduct reconciliation for all three (CCD, Referral Note, Discharge Summary), generate new CCDA

The test was designed to ensure that a user could enter, access, and/or modify data within areas 1 through 7. For item 8, Clinical Support, the focus was on ensuring that as data was entered or modified, the proper alerts would appear to ensure the user could make an informed decision.

Risk Assessment

Each task was assessed a risk rating of low, moderate, or high, based on the likelihood of error combined with the relative patient safety impact of any potential error.

Task ID	Task Description	Likelihood of Error	Patient Safety Impact of Error	Overall Risk Rating
Criteria 170.315(a)(1) - CPOE Medications				
A.1.1	Computerized provider order entry (CPOE) – create medication order	Moderate	High	High
A1.2	Computerized provider order entry (CPOE) – change medication order	Low	High	High
A1.3	Computerized provider order entry (CPOE) – display medication order	Low	Moderate	Moderate
Criteria 170.315(a)(2) - CPOE Laboratory				
A2.1	Computerized provider order entry (CPOE) – create laboratory order	Moderate	Moderate	Moderate
A2.2	Computerized provider order entry (CPOE) – change laboratory order	Low	Moderate	Moderate
A2.3	Computerized provider order entry (CPOE) – display laboratory order	Low	Low	Low
Criteria 170.315(a)(3) - CPOE Radiology				
A3.1	Computerized provider order entry (CPOE) – create diagnostic imaging order	Moderate	Moderate	Moderate
A3.2	Computerized provider order entry (CPOE) – change diagnostic imaging order	Low	Moderate	Moderate
A3.3	Computerized provider order entry (CPOE) – display diagnostic imaging order	Low	Low	Low
Criteria 170.315(a)(4) - Drug-drug, Drug-allergy Interaction Checks				
A4.1	Drug-drug, drug-allergy interaction checks for CPOE - trigger a drug-drug interaction alert	Low	High	Moderate
A4.2	Drug-drug, drug-allergy interaction checks for CPOE - trigger a drug-allergy interaction alert	Low	High	Moderate
A4.3	Drug-drug, drug-allergy interaction checks for CPOE - adjust drug-drug severity alert threshold	Moderate	High	High
Criteria 170.315(a)(5) - Demographics				
A5.1	Demographics - enter	Low	Moderate	Moderate
A5.2	Demographics - change	Low	Low	Low
A5.3	Demographics - display	Low	Low	Low
Criteria 170.315(a)(6) - Problem List				
A6.1	Problem list - enter problem	Moderate	Moderate	Moderate
A6.2	Problem list - change problem	Moderate	Moderate	Moderate
A6.3	Problem list - display active and historical problem list	Low	Moderate	Moderate
Criteria 170.315(a)(7) - Medication List				
A7.1	Medication list - enter medication list order	Moderate	High	High
A7.2	Medication list - change medication list order	Low	High	High
A7.3	Medication list - display active and historical medication list	Low	Moderate	Moderate
Criteria 170.315(a)(8) - Medication Allergy List				
A8.1	Medication allergy list - enter medication allergy	Moderate	High	High
A8.2	Medication allergy list - change medication allergy	Low	High	High
A8.3	Medication allergy list - display active and historical medication allergy list	Low	High	High
Criteria 170.315(a)(9) - Clinical Decision Support				
A9.1	Clinical decision support (CDS) - add a CDS intervention	Moderate	High	High
A9.2	Clinical decision support (CDS) - trigger a CDS intervention	Low	High	High
A9.3	Clinical decision support (CDS) - view the intervention/resource information using the Infobutton standard for data elements in the problem list, medication list, and demographics	High	High	High
A9.4	Clinical decision support (CDS) - trigger and view CDS intervention information and resources from transition of care	Moderate	High	High
A9.5	Clinical decision support (CDS) - access the following attributes for one of the triggered CDS interventions/resources: bibliographic citation, developer, funding source, release/revision date	Low	Moderate	Moderate
Criteria 170.315(a)(14) - Implantable Device List				
A14.1	Implantable device list - enter implantable device	Low	Moderate	Moderate
A14.2	Implantable device list - change implantable device	Low	Moderate	Moderate
A14.3	Implantable device list - display implantable device list	Low	Moderate	Moderate
Criteria 170.315(b)(2) - Clinical Information Reconciliation and Incorporation				
B2.1	Clinical information reconciliation and incorporation - medication list reconciliation	Moderate	High	High
B2.2	Clinical information reconciliation and incorporation - create CCDA with reconciled data	High	High	High

Procedure

The tests were facilitated by the iCare Meaningful Use Project Manager and senior management. To ensure consistency in communication to all participants, the same staff member delivered the same level of minimal product training in a group environment to all participants. To ensure that proper attention was given to the test groups, the number or participants was kept to a small number for each session.

Participants were instructed to perform each given task as quickly as possible and that if they experienced uncertainty in how to perform a given task to alert the facilitator as soon as possible. Only questions requesting clarification of a task were addressed and only after the specific task section was completed could group discussion occur.

Although each task was timed, the participants were allowed to complete each section, without having the time limits announced. It was decided that this would result in fewer mistakes as a result of stress. The task time was recorded once the participant indicated they had successfully completed the task.

Test Locations

The test areas were quiet and included individual workstations for each participant. Three of the participants were tested in a group environment on a college campus, two were tested at the iCare facility in separate rooms, and one participant was tested via a webcast hosted by the project manager while the participant sat at home. These various locations were chosen to simulate real working environments by potential users.

Test Environment

The application has been designed as a cloud (web) based product which allows the user to use it via any type of computer or mobile device. The application defaults were set by the iCare team - the participants were not given the administrative permission to make changes to the default settings unless required by a test segment. Each user was allowed to select the web browser that he or she was most comfortable with or being used by the company that was allowing the test to occur at their site – only two Internet browsers were selected for the test groups.

Test Forms and Tools

Two forms were used for testing:

1. The test form consisted of a list of patients with problems, allergies, orders (medications, labs, and radiology), and progress notes.

2. Test Usability Scoring Sheet

Examples of these forms can be found in the Appendix section.

Participants Instructions

The testing was introduced following two specific scenarios:

1. As an introduction to functionality testing to new employees.

2. As a baseline evaluation for new users to provide testing and feedback on the product design.

The following statement was made to both groups:

Thank you for volunteering to perform new user testing on the iCare EHR. Your ability to perform the tasks presented in this test are not a reflection on your knowledge of computer software, the results of this test will assist us in gaining knowledge on the ease of use of the product and identify any areas in the design that require modifications or improvement. You will be given a patient record to use for entering, changing, and accessing data within the record. In some cases, based on your entry, we are looking to see how the application responses, such as with warning messages or the requirement of you to perform another step to complete the task you have been assigned.

If you face any issues or have general questions regarding the objective of the task, please feel free to ask me, however be aware that I will not encourage or participate in a discussion of how to perform a task until that task has been completed or the task could not be performed.

Usability Metrics

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 the iCare EHR by measuring participant success rates and errors

2. Efficiency of the iCare EHR by measuring the path deviations

3. Satisfaction with the iCare EHR by measuring ease of use ratings

Data Scoring

The following table provides information regarding how the tasks were scored.

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.
Effectiveness: Task Failure	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, the task was counted as a "Failure." The total number of errors was calculated for each task and then divided by the total number of times that task was attempted.
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.
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was measured by administering a simple post-task question. After each task, the participant was asked to rate

	"Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy).

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. [NOTE: All participants followed session and task instructions – therefore no exclusions were required.]

Task ID	Task Description	Task Success Mean (%)	Task Success Std Dev (%)	Task Path Deviation Observed #	Task Path Deviation Optimal #	Task Time Mean (seconds)	Task Time Standard Deviation (seconds)	Task Time Deviation Mean Observed Seconds	Task Time Deviation Mean Optimal Seconds	Task Errors Mean(%)	Task Errors Std Dev %	Task Rating Scale Type	Task Rating	Task Rating Standard Deviation
Criteria 170.315(a)(1) - CPOE Medications														
A.1.1	Computerized provider order entry (CPOE) – create medication order	100	0	18	18	115	19	19	80	0	0	Likert	4.9	0.32
A1.2	Computerized provider order entry (CPOE) – change medication order	100	0	18	18	104	19	19	70	0	0	Likert	4.8	0.42
A1.3	Computerized provider order entry (CPOE) – display medication order	100	0	9	9	61	7	7	40	0	0	Likert	4.9	0.32
Criteria 170.315(a)(2) - CPOE Laboratory														
A2.1	Computerized provider order entry (CPOE) – create laboratory order	100	0	10	10	124	22	22	72	0	0	Likert	4.7	0.48
A2.2	Computerized provider order entry (CPOE) – change laboratory order	100	0	11	11	125	23	23	80	0.1	0.32	Likert	4.6	0.52
A2.3	Computerized provider order entry (CPOE) – display laboratory order	100	0	8	8	57	10	10	48	0	0	Likert	4.6	0.52
Criteria 170.315(a)(3) - CPOE Radiology														
A3.1	Computerized provider order entry (CPOE) – create diagnostic imaging order	100	0	14	14	155	32	32	87	0.2	0.42	Likert	4.5	0.53
A3.2	Computerized provider order entry (CPOE) – change diagnostic imaging order	90	31.62	13	13	142	23	23	81	0.1	0.32	Likert	4.2	1.23
A3.3	Computerized provider order entry (CPOE) – display diagnostic imaging order	100	0	8	8	58	9	9	47	0	0	Likert	4.6	0.52
Criteria 170.315(a)(4) - Drug-drug, Drug-allergy Interaction Checks														
A4.1	Drug-drug, drug-allergy interaction checks for CPOE - trigger a drug-drug interaction alert	90	31.62	16	16	173	30	30	120	0.2	0.42	Likert	4.3	1.25
A4.2	Drug-drug, drug-allergy interaction checks for CPOE - trigger a drug-allergy interaction alert	90	31.62	16	16	176	35	35	120	0.2	0.42	Likert	4.4	1.26
A4.3	Drug-drug, drug-allergy interaction checks for CPOE - adjust drug-drug severity alert threshold	90	31.62	24	23	158	20	20	107	0.2	0.42	Likert	4.5	1.27
Criteria 170.315(a)(5) - Demographics														
A5.1	Demographics - enter	90	31.62	25	25	313	53	53	214	0.2	0.42	Likert	4.6	1.27
A5.2	Demographics - change	90	31.62	19	19	316	50	50	215	0.2	0.42	Likert	4.5	1.27
A5.3	Demographics - display	90	31.62	17	19	135	41	41	97	0.2	0.42	Likert	4.5	1.27
Criteria 170.315(a)(6) - Problem List														
A6.1	Problem list - enter problem	100	0	13	13	132	23	23	90	0	0	Likert	4.7	0.48
A6.2	Problem list - change problem	100	0	14	14	111	19	19	87	0	0	Likert	4.8	0.42
A6.3	Problem list - display active and historical problem list	100	0	8	8	77	14	14	60	0	0	Likert	4.8	0.42
Criteria 170.315(a)(7) - Medication List														
A7.1	Medication list - enter medication list order	100	0	19	19	153	19	19	120	0	0	Likert	4.8	0.42
A7.2	Medication list - change medication list order	100	0	13	13	110	26	26	80	0	0	Likert	4.9	0.32
A7.3	Medication list - display active and historical medication list	100	0	10	10	66	16	16	46	0	0	Likert	5	0
Criteria 170.315(a)(8) - Medication Allergy List														
A8.1	Medication allergy list - enter medication allergy	90	31.62	15	15	164	31	31	110	0.2	0.42	Likert	4.5	1.27
A8.2	Medication allergy list - change medication allergy	90	31.62	12	12	127	24	24	87	0.1	0.32	Likert	4.4	1.27
A8.3	Medication allergy list - display active and historical medication allergy list	90	31.62	8	8	88	18	18	62	0.2	0.42	Likert	4.5	1.27
Criteria 170.315(a)(9) - Clinical Decision Support														
A9.1	Clinical decision support (CDS) - add a CDS intervention and/or reference resource for each of the required elements and combination of elements	90	31.62	12	12	104	16	16	60	0.1	0.32	Likert	4.6	1.27
A9.2	Clinical decision support (CDS) - trigger the CDS interventions/resources added using the applicable data elements from each of the required elements and combination of elements	90	31.62	12	12	97	21	21	65	0.1	0.32	Likert	4.6	1.27
A9.3	Clinical decision support (CDS) - view the intervention/resource information using the Infobutton standard for data elements in the problem list, medication list, and demographics	90	31.62	12	12	66	11	11	24	0.1	0.32	Likert	4.3	1.34
A9.4	Clinical decision support (CDS) - trigger and view CDS intervention information and resources from transition of care	90	31.62	16	16	145	13	13	118	0.1	0.32	Likert	4.3	1.34
A9.5	Clinical decision support (CDS) - access the following attributes for one of the triggered CDS interventions/resources: bibliographic citation, developer, funding source, release/revision date	90	31.62	7	7	39	7	7	22	0.1	0.32	Likert	4.3	1.34
Criteria 170.315(a)(14) - Implantable Device List														
A14.1	Implantable device list - enter implantable device	90	31.62	13	13	141	20	20	94	0.1	0.32	Likert	4.5	1.27
A14.2	Implantable device list - change implantable device	90	31.62	12	12	91	17	17	61	0.1	0.32	Likert	4.6	1.27
A14.3	Implantable device list - display implantable device list	90	31.62	11	11	81	14	14	59	0.1	0.32	Likert	4.6	1.27
Criteria 170.315(b)(2) - Clinical Information Reconciliation and Incorporation														
B2.1	Clinical information reconciliation and incorporation - medication list reconciliation	90	31.62	32	32	273	50	50	180	0.1	0.32	Likert	4.3	1.25
B2.2	Clinical information reconciliation and incorporation - create CCDA with reconciled data	90	31.62	12	12	92	19	19	60	0.1	0.32	Likert	4.5	1.27

Discussion of the Findings

1. Effectiveness

Based on a combination of the testing results and the feedback from the participants it has been determined that the iCare EHR is an application that supports a workflow that provides an effective means for placing orders pertaining to patient care, documenting this care in a manner that is easy to understand, and accessing information stored in the patient's chart.

2. Efficiency

According to the findings of the test, combined with feedback from the test participants, the cloud based technology of the iCare EHR provides the an efficient process for documenting patient care, placing orders (medication, laboratory, and radiology/imaging), as well as accessing and modifying the data. The information input into the system initiates an action or can be accessed in real time – reducing the margin for error and increasing patient care productivity.

3. Satisfaction

The test participants reported that they found the iCare application as an easy to understand and use product. Most area patient chart areas in application are clearly labelled and due to the stable design (for instance the placement and functionality of the Action button) the application reduces the learning curve for using the software and supports a consistent means of performing most actions.

4. Error Rate and Deviations

Each participant was allowed to attempt to complete a task for a minimum of two attempts or make the self-decision to stop trying before the task completion was considered a failure. [NOTE: No participants made the decision to stop attempting to complete a task; when a deviation occurred the participants, on their own accord, made the decision to stop, rethink the path that they were following and started the task again.]

5. Major Findings

The participants reported

- That the design of the user screens remains consistent throughout the application which supports the ability for users to quickly gain a level of proficiency navigating through the system.

- Most sections within the patient chart labelled based on the data that is contained in the screens or the functionality that is to be performed.

- Menus presented from the Action button apply to the functionality the section is designed to support – this allowed the participants to feel as though the software was easy to learn without extensive training.

- The participants felt that the iCare EHR was designed with patient safety in mind

    – The pop-up intervention screens provided the user with data needed for decision-making, however the application does not force a workflow or decision on the user.

- The user liked the fact that the menu options available to the end user is based on the permissions of the user profiles assigned to the user. In this way, the software can be configured to address the needs and roles of the users.

6. Areas for Improvement

The participants provided the following feedback regarding areas of possible improvement:

- The options that are available to the end user are controlled by the user profile configuration options however, it would be useful if the configurations could be made apparent to new users.
- There is a need to include vital sign interventions in the Notification List area of the software instead of making the user open the patient chart to see an intervention. This type of notification is already present for critical lab results.

Appendices

A. Sample recruiting Screener

Recruiting Script for Recruiting Participants

Hello, I am representing iCare.com. We are recruiting individuals to participate in a usability study for our electronic health record. We would like to ask you a few questions to see if you qualify and if would like to participate. This should only take a few minutes of your time. This is strictly for research purposes. Can I ask you a few questions?

1. Have you participated in a focus group or usability test in the past *6* months?

2. Which of the following best describes your age? [23 to 39; 40 to 59; 60 - to 74; 75 and older]

3.. Do you require any assistive technologies to use a computer?

Professional Demographics

4. What is your current position and title? (Must be healthcare provider)

☐   RN: Specialty

☐   Physician: Specialty _

☐   Resident: Specialty

☐   Administrative Staff

☐   Other

5. How long have you held this position?

6. Describe your work location (or affiliation) and environment? [e.g., private practice, health system, government clinic, etc.]

7. Which of the following describes your highest level of education? [e.g., high school graduate/GED, some college, college graduate (RN, BSN), postgraduate (MD/PhD), other (explain)]

Computer Expertise

8. Besides reading email, what professional activities do you do on the computer? [e.g., access EHR, research; reading news; shopping/banking; digital pictures; programming/word processing, etc.]

9. About how many hours per week do you spend on the computer? [e.g., 0 to 10, 11 to 25, 26+ hours per week]

10. What computer platform do you usually use? [e.g., Mac, Windows, etc.]

11. What Internet browser(s) do you usually use? [e.g., Firefox, IE, AOL, etc.]

12. In the last month, how often have you used an electronic health record?

13. How many years have you used an electronic health record?

14. How many EHRs do you use or are you familiar with?

15. How does your work environment patient records?

☐   On paper

☐   Some paper, some electronic

☐   All electronic

Contact Information

Those are all the questions I have for you. Your background matches the people we're looking for. Would you be able to participate on [date, time]?

May I get your contact information?
▪   Name of participant:

▪   Address:

▪   City, State, Zip:

▪   Daytime phone number:

▪   Evening phone number:

▪   Alternate [cell] phone number:

B. Participant Demographics

The participants in this study were selected based on their availability and expressed interest in using the iCare EHR.

C. Nondisclosure Agreement and Informed Content

Non-Disclosure Agreement

THIS AGREEMENT is entered into as of _ _, *2019*, between ("the Participant") and the testing organization *iCare.com, Inc.* located 401 E. Las Olas Blvd., Ste 1400, Fort Lauderdale, FL 33301

The Participant acknowledges his or her voluntary participation in today's usability study may bring the Participant into possession of Confidential Information. The term "Confidential Information" means all technical and commercial information of a proprietary or confidential nature which is disclosed by *Test Company*, or otherwise acquired by the Participant, in the course of today's study.

By way of illustration, but not limitation, Confidential Information includes trade secrets, processes, formulae, data, know-how, products, designs, drawings, computer aided design files and other computer files, computer software, ideas, improvements, inventions, training methods and materials, marketing techniques, plans, strategies, budgets, financial information, or forecasts.
Any information the Participant acquires relating to this product during this study is confidential and proprietary to *iCare.com, Inc.* and is being disclosed solely for the purposes of the Participant's participation in today's usability study. By signing this form the Participant acknowledges that will not disclose this confidential information obtained today to anyone else or any other organizations.

Participant's printed name:

Signature:

Date:

Informed Consent

iCare.com, Inc. 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. At the conclusion of the test, you will be compensated for your time.

Agreement

I understand and agree that as a voluntary participant in the present study conducted by *iCare.com, Inc.* I am free to withdraw consent or discontinue participation at any time. I understand and agree to participate in the study conducted by the *iCare.com, Inc.*.

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 *iCare.com, Inc.* and *iCare.com, Inc.'s* client. 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:

D. Moderator's Guide

Administrator _____
Data Logger   _____
Date   _____
Time   _____
Participant # _____
Location   _____

Prior to testing
- Confirm schedule with Participants
- Ensure EHRUT lab environment is running properly
- Ensure lab and data recording equipment is running properly

Prior to each participant:
- Reset application
- Start session recordings with *tool*

Prior to each task:
- Reset application to starting point for next task

After each participant:
- End session recordings with *tool*

Orientation (*X* minutes)

Thank you for participating in this study. Our session today will last ***XX* 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 (*X* minutes)

What is your job title / appointment?

How long have you been working in this role?

What are some of your main responsibilities?

Tell me about your experience with electronic health records.

Usability Testing Tasks and Paths

CPOE Order Medication §170.314(a)(1)	

1   **Create Order**

*Login-> Click No in the Pop up-> Type **R83860**-> Click Search->Double Click on Patient Record-> On Order Screen Left lower Panel Click on + sign Pharmacy Medications-> Click Unit Dose Medications-> Type Aceta... -> Select ACETAMINOPHEN 325mg -> Select Dose 325 mg-> Frequency: Type BID and Select from drop down-> Click Perform Drug Check-> Accept Order-> Click on right upper corner User Name -> Click Log out*

2   *Change Order*

Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> On Order Screen Select Order Acetaminophen 325 mg-> From Actions menu select Change -> Frequency: Type DAILY and Select DAILY PRN from drop down-> Click Perform Drug Check-> Accept Order-> Log out

3   *Display Order with Change*

Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> On Order Screen Point the Mouse o Order column content and view the content-> Log out

CPOE Order Laboratory §170.314(a)(2)	

4   **Create Order**

Login-> Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> On Order Screen Left lower Panel Click on Laboratory-> Type CBC in Available Lab Test field -> Select CBC Profile->Accept Order-> Log out

5   *Change Order*

Login-> Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> On Order Screen select Lab CBC Profile-> Select Change from Actions Menu-> Type LIPID in Available Lab Test field -> Select Lipid Profile->Accept Order-> Log out

6   *Display Order with Change*

Login->Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> On Order Screen point the cursor on the content for Lab Order in Order column and view the content-> Log out

CPOE Order Imaging Order §170.314(a)(3)

7   Create Order

Login->Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> On Order Screen Left lower Panel Click on Imaging ->Select Imaging type(CT Scan)->select Imaging Procedure(CT ABD & PELVIS W W/O CONTRAST) ->Select reason for study->Select Date of Desired->Select category-> Click on Save button->Log out

8   *Change Order*

Login->Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> on Orders screen select Imaging order->From Action menu select change->Change Imaging type as Mammography ->Save->log out

9   *Display Order with Change*

Login->Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> On Order Screen point the cursor on the content for Imaging order in Order column and view the content-> Log out

Drug-Drug, Drug- Allergy Intervention §170.314(a)(4)

10   *Trigger a Drug-Drug Interaction*

Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> On Order Screen Left lower Panel Click on + sign Pharmacy Medications-> Click Unit Dose Medications-> Type Warfarin.. -> Select Warfarin Tab -> Dose 2.5 mg-> Frequency: Type BID and Select from drop down-> Click Perform Drug Check-> View the Drug-Drug Interaction information-> View the legend for Severity level and Note the level of Severity-> Cancel and Log out

11   *Trigger a Drug-Allergy Interaction alert*

Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> On Order Screen Left lower Panel Click on + sign Pharmacy Medications-> Click Unit Dose Medications-> Type **Ibuprofen***.. -> Select Ibuprofen12 Tab -> Dose 400 mg-> Frequency: Type BID and Select from drop down-> Click Perform Drug Check-> View the Drug-Allergy interaction alert for Ibuprofen-> Cancel and Log out*

| 12 | ***Adjust Drug-Drug Interaction Severity for the Displayed Drug*** |

Login-> Press OK on the Pop up screen-> Click on Admin-> Click on Medication & Pharmacy -> Click on Drug Interaction Severity-> Check the Check box for option ' Severe - Do Not Take These Drugs Together' -> Click Save

Click on the Patient Chart shown next to Home-> On Order Screen Left lower Panel Click on + sign Pharmacy Medications-> Click Unit Dose Medications-> Type Warfarin.. -> Select Warfarin Tab -> Dose 2.5 mg-> Frequency: Type BID and Select from drop down-> Click Perform Drug Check-> There will be no Drug-Drug interaction alert.: See the text No Interaction..-> Cancel and Log out

| | **Demographics §170.314(a)(5)** |
| 13 | ***Record*** |

Enter User Name and Password and Click Login-> Click + Sign next to Home and Select Register-> Enter
First Name : MERVIN,
Last Name : WILMAN
DOB: 06/01/1967
Select the following
Gender: Male
Race: White
Ethnicity: Not Hispanic or Latino
Preferred Language: English
Do You Think Yourself as: Straight or Heterosexual
What is your current Gender Identity: Male
Click Save
Click Home Tab-> enter Name WILMAN,MERVIN-> Click Search-> Double click the record-> Click Patient Info Tab-> Click Death Info from lower section-> Type Cardiac Arrest in Preliminary cause of Death-> Enter Date; Current Date -> Click Save -> Log out

| 14 | ***Change*** |

*Enter User Name and Password and Click Login-> Enter **WILMAN,MERVIN** and Search-> Double click on the record-> Click Patient Info-> and Change*
First Name : CATHERINE,
Last Name : MERVIN
DOB: 06/01/1992
Select the following
Gender: Female
Race: Asian
Ethnicity: Hispanic or Latino
Preferred Language: Spanish
Do You Think Yourself as: Don't Know
What is your current Gender Identity: Female
Cause of Death: Respiratory Arrest
Date Of Death: 12/12/2019
Click Save-> Log out

15	*Display*

Enter User Name and Password and Click Login-> Enter MERVIN,CATHERINE and Search-> Double click on the record-> Click Patient Info->
View the data
First Name : CATHERINE,
Last Name : MERVIN
DOB: 06/01/1992
Select the following
Gender: Female
Race: Asian
Ethnicity: Hispanic or Latino
Preferred Language: Spanish
Do You Think Yourself as: Don't Know
What is your current Gender Identity: Female
Cause of Death: Respiratory Arrest
Date Of Death: 12/12/2019
Log out

Problem List §170.314(a)(6)

16	**Create Problem List**

*Login->Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> Select Problems tab ->Go to Action Menu->select Create New Problem->Type problem(Fever)-> Click on search -> select **Fever 106 degrees F or over** ->Click on OK -> Select problem status-> click on OK ->Log out*

17	*Change Problem List*

*Login-> Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> Select Problems tab ->Select added problem ->Go to Action Menu->select Change Problem->Click on edit icon next to problem name->Type problem(Headache)-> Click on search -> select **Headache above the eye region** ->Click on OK -> Change problem status-> click on OK ->Log out*

18	*Display Problem List with Change*

Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> On Problem Screen point the cursor on the content for Probelm view content->Log Out

Medication List §170.314(a)(7)

19 *Create Medication List*

Login->Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> Select Meds tab ->Go to Action Menu -> Select New Medication-> Type Acetamin.. -> Select Dose 325 mg-> Frequency: Type BID and Select from drop down-> Click Perform Drug Check-> Accept Order-> Go to Orders->Select Medication Order-> Go to Action->Select Sign Selected->Accept Order->Enter E-signature(123456)->Click on OK button->Go to Meds tab->Verify Medication is displayed->Log Out

20 *Change Medication List*

Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> Select Meds tab ->Go to Action Menu -> Select Change >Change Frequency: type Daily and select from drop down ->Click perform Drug Check->Accept Order->Log Out

21 *Display Medication List*

Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> Select Meds tab ->hover on Meds order content will display for meds order->Log Out

Medication Allergy List §170.314(a)(8)

22 *Create Allergy List*

*Login-> Type **R83860**-> Click Search->Double Click on Patient Record-> Select Allergy tab ->Go to Action Menu ->Click on Add Allergy->Type IBUPROFEN and select same from National Drug File-Trade Name>select Obeserved->select nature of reaction (Allergy)->Select Severity (Moderate)->Select Reaction date->Select Sign/Symptoms(Hives)Drag to the Selected Symptoms box select Date->Enter Comments->Click on OK ->Log Out*

23 *Change Allergy List*

Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> Select Allergy tab ->Go to Action Menu ->Click on Edit Allergy->Edit Severity (High)->Click on ok->Log Out

24 *Display Allergy List*

Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> Select Allergy tab->hover on Allergy order content will display for Allergy ->Log Out

	Clinical Decision Support §170.314(a)(9)
25	**Add a CDS intervention**

1.Open the Admin Screen - Clinical Reminder and Select current user
2. Search and select the following reminder for the elements and click on the right arrow
Problem list: HbA1c for Diabetes
Medication list: WARFARIN
At least one Demographic: Pneumococcal PPSV23(Pneumovax) for age > 65
Laboratory Test: Control Your Cholesterol
Vital Signs: Body Mass Index >25
Medication Allergy List: Select Penicillin Allergy from Allergy screen
And a combination of at least 2 of the elements listed above (Problem & Lab) - Blood Pressure >= 140/90 mmHg AND Race = Black or African American
Click Apply

26	**Trigger a CDS intervention**

From Problem Screen Add Problem- Diabetes one ICD (ICD 10 8-13)
View the cover sheet after refresh
Order Screen_ Order WARFARIN and Sign
View the Cover sheet after Refresh"
Patient Info_ enter/edit DOB 1952 (Age > 65)
View the Cover sheet after Refresh
Home _ Laboratory Screen_ Select Result Entry from Actions screen and Search Test Patient 1 by Admission Date
Select the Test Patient 1 (double click the record)
Direct Entry_Test_Cholesterol LDL
Add result > 99 , Provider , Date and Time and save.
View the Cover sheet after Refresh
Vital Signs Screen_ Add Height 177 cm and Height 92 kg
View the Cover sheet after Refresh
Click on the Posting icon next Patient Name, which will have alphabet 'A' shown.
View the Medication Allergy Name in the Pop up screen.
For test patient 2
Add Vitals - Blood Pressure = 140/90
On patient info, set Race to Black or African American
View the Cover Sheet alert

27	**View CDS intervention Information and Resources**

Open Reminder screen- Click on the Clock icon near Patient Name or Reminder Tab
Select HbA1c for Diabetes and view the maintenance from view menu.
Click on the URL for the details.
Open Reminder screen- Click on the Clock icon near Patient Name or Reminder Tab
Select WARFARIN and view the maintenance from view menu.
Click on the URL for the details.
Open Reminder screen- Click on the Clock icon near Patient Name or Reminder Tab

*Select Pneumococcal PPV23 and select Reminder Inquiry from View Menu
and Click on the URL provided.*

27 Trigger and view CDS intervention from transition of care

*Login-> trigger the CDS interventions/resources based on data elements in the problem list,
medication list, and medication allergy list by incorporating patient information from a transition of
care/referral summary / click infobutton / Select Test Patient 3 (Inpatient) / Link the same
document with Test Patient 3*
1. Reconciliation- Reconcile Problem List, Medication List, Allergy List
2. Sign the reconciled medication order from Orders Screen
View Cover sheet for Test Patient 3
 a. Click the Posting ICON with letter 'A' to view the reminder triggered by the transition of care
 *b. View the HbA1c for Diabetes, WARFARIN reminders on Cover Sheet View intervention resources
and attributes*

28 Access the following attributes for one of the triggered CDS interventions/resources: bibliographic citation, developer, funding source, release/revision date

*Reminder screen- Select HbA1c for Diabetes and click on Reminder Maintenance from View menu
and click on the URLs shown for Bibliographic citation, Developer, Funding Source and
Release/revision date one by one*

Implantable Devices List §170.314(a)(14)

29 Record UDI

*Enter User Name and Password and Click Login-> Type **R83860**-> Click Search->Double Click on
Patient Record-> Click Patient Info tab ->Click on Actions and select Implantable Devices->Click on
'Add' button-> copy and paste **(01)00643169007222(17)160128(21)BLC200461H** in the UDI field->
Click Verify FDA -> Enter Implant Date 09/11/2017-> Click Save -> Close screen ->Log out*

30 Change UDI

*Enter User Name and Password and Click Login-> Type **R83860**-> Click Search->Double Click on
Patient Record-> Click Patient Info tab ->Click on Actions and select Implantable Devices->Select the
record from the grid-> Change the Implant Date to 11/08/2019-> Click Save->Close screen ->Log out*

31 Access UDI

*Enter User Name and Password and Click Login-> Type **R83860**-> Click Search->Double Click on
Patient Record-> Click Patient Info tab ->Click on Actions and select Implantable Devices->Select the
record from the grid-> View the record with implant date 11/08/2019-> Click Cancel->Log out*

	Clinical Information Reconciliation and Incorporation §170.314(b)(2)
32	**Medication List Reconciliation**

Login ->Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> Click Med tab-> Click Action Menu and select Create Reconcile List-> Select the file from the Grid shown-> Select CLINDAMYCIN from left panel, drag and drop to right side first grid-> Frequency type BID -> Select BID-> Click Perform Drug check button-> Click Accept-> Click Actions Menu-> Select Complete Reconciliation-> Click Accept Order->in eSignature field type 123456 and press Accept->Press OK->Log out

33	**Create CCDA with Reconciled data**

Login-> Press OK on the Pop up screen-> Click on the Patient Chart shown next to Home-> Click Reports tab-> Click Clinical Summary-> Select Continuity of Care-> Select the Date-> Log out

Each participant was taken to the starting point of the each task and after the task completion the Success with three options as above was recorded. The time taken and the comments were also recorded as per the format above.

Each Task had the Optimal Path defined and it recorded if the participant followed the correct path or had minor or major deviation as shown in the format above.

Observed Comments/verbalizations were also recorded. Participant rated each task as per Likert scale. From Very Difficult(1) to Very Easy(5)

The tasks selected for this test are based on the criteria required for the iCare EHR to obtain certification as a completed inpatient EHR. The product functionality has been designed to allow the user to select a menu command from the "Action" button or select from a set of menu options that are always visible on screen that has been selected. The tasks are reflected on the screen that is labelled by a tab for the item to be found such as Orders, Medications, etc. Once the user selects the area they wish to work in, the Action button menu items listed are for the screen the user has selected.

Below are samples of the optimal path for navigating through the application.

Record Laboratory Order

Orders Tab -> Write Orders->Laboratory -> Available Lab Tests Field -> Search and Select LDL-> Complete Fields (Collection Sample, Collection Date, etc) -> Click OK Button

Record Medication Allergy List

Allergies Tab -> Click Actions Button -> Select Add Allergy -> Select Observed/Historical ->Enter Allergy Name (Penicillin) and search -> Select Penicillin from list-> Select Nature of Reaction -> Enter Severity -> Enter Reaction Date-> Select Sign/Symptoms drag and drop and enter date -> Add comment -> Click OK Button

Drug-Drug, Drug- Allergy List Interventions

The user will follow the process for ordering a medication, however in order to place the order, first the user must click a button labelled "Perform Drug Check" which will check drug-drug interaction, medication allergies, dosage limits, and drug order duplications.

Orders Tab -> Write Orders-> Pharmacy Orders-> Unit Dose Medication->Enter WARFARIN and Select -> Complete Fields from drop down menus (Dosage, Route, Frequency, Priority)-> Click Perform Drug Check Button -> Order Check Screen will appear for review with Drug-Drug interaction and Drug- allergy alerts and intervention. The user has the opportunity to Cancel or Accept the Order.

Final Questions (*X Minutes*)

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

E. System Usability Scale Questionnaire

	1	2	3	4	5
1. I think that I would like to use this system frequently	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