

Intellicure EHR
Version 7.0

Usability Test Report of Intellicure EHR

Report based on NISTIR 7742 Customized Common Industry Format Template for Electronic Health
Record Usability Testing

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Report Prepared by Intellicure, Inc.

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1. Executive Summary

In November and December of 2018, a usability study of IntellicureEHR 7.0 from Intellicure, Inc, an ambulatory electronic health record software, was conducted remotely by Intellicure User Experience researchers. The purpose of this summative study was to test and validate the usability of the current user interface and provide evidence of usability in IntellicureEHR.

During the usability test, 5 physicians/providers and 5 nurses matching the target demographic criteria served as participants in the usability test. Each participant used IntellicureEHR in simulated, but representative role-specific tasks.

This study collected performance data on 19 tasks typically conducted on an EHR by physicians/providers and nurses. The tasks are correlated to five certification criteria in 45 CFR Part 170 Subpart C of the Health Information Technology: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications:

- §170.315(a)(2) Computerized Provider Order Entry – Laboratory
- §170.315(a)(5) Demographics
- §170.315(a)(6) Problem List
- §170.315(a)(9) Clinical Decision Support
- §170.315(a)(14) Implantable Device List

The remote, one-on-one usability test was 30 minutes for physicians and nurses. During each usability test, the administrator greeted the participant. Each participant was read a request for informed consent/release and asked to give their verbal consent, which was recorded (see Appendix C – Recording Consent).

All participants had prior experience with some version of an Electronic Health Record. Training videos on new features were distributed to users prior to the test. The training videos were consistent with online training provided to actual end users.

The administrator introduced the test and instructed participants to complete a series of tasks (given one at a time) using the EHR Under Test (EHRUT).

During each test, the participant's screens and audio were recorded electronically and the data logger recorded notes on paper and electronically. The recordings were later analyzed to determine task times and evaluate user performance.

All participant data was de-identified—no correlation 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 sent a \$25 gift card in appreciation for their time.

The process used was based on NISTIR 7741¹ and various recommended metrics were used to evaluate the usability of the EHRUT. Use was in accordance with the examples set forth in the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*. The following quantitative data were collected for each participant:

- Number of tasks successfully completed within the allotted time without assistance

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- Time to complete each task
- Number and types of errors
- Path deviations
- Participant's familiarity, ease-of-use, and satisfaction ratings of the system and its components
- System Usability Scale (SUS)

In addition, results include the following qualitative observations:

- Major findings
- Areas for improvement
- Participant's verbalizations

The results from the System Usability Scale (SUS)² scored the subjective satisfaction with the system based on performance with these tasks to be:

- Overall SUS for both providers and nurses:
- SUS based on provider task performance:
- SUS based on nurse task performance:

2. Introduction

The EHR Under Test (EHRUT) tested for this study was IntellicureEHR 7.0, an ambulatory electronic health record software. Designed to present medical information to healthcare providers in an outpatient setting for various specialties, IntellicureEHR consists of a comprehensive electronic clinical system used to create, store, and retrieve patient data. Intended users of IntellicureEHR are doctors, nurse practitioners, physician assistants, nurses, therapists, and anyone entering or accessing clinical data at an ambulatory medical practice. The usability testing attempted to represent realistic exercises and conditions that occur in a typical medical practice environment.

The purpose of this study was to test and validate the usability of the current user interface and provide evidence of usability in the EHRUT. To this end, measures of effectiveness, efficiency, and user satisfaction were captured during the usability testing, such as task success, time on task, and task group ratings.

3. Method

Participants

A total of 10 participants were tested on IntellicureEHR. Intellicure User Experience researchers coordinated the recruiting of participants with the administrators of healthcare organizations. The request to the administrators described end-user roles and the administrators identified matching participants. 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 A – Sample Recruiting screener.

Participants in the test were physicians, physician assistants, nurse practitioners, nurses, and therapists. All participants were current end users of IntellicureEHR working in ambulatory settings, varying in specialty, and ranging in years of experience with IntellicureEHR. Users with clinical decision-making

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privileges were scheduled as physician/provider participants and users with non-provider care privileges were scheduled as nurse/therapist’s participants.

Participants were sent a \$25 gift card in appreciation for their participation. For new features being tested, participants were given the opportunity to have the same orientation and level of training as the actual end users would have received.

Recruited participants had a mix of backgrounds and demographic characteristics conforming to the recruitment screener. Table 1 lists participants by characteristics, including occupation/role and product experience. Participant names were replaced with Participant IDs so that an individual’s data cannot be tied back to individual identities.

Total Number and Description of Participants

The total number of participants was 10. Their descriptions are indicated in the table below:

Participant Identifier	Gender	Age	Education	Occupation/ Role	Professional Experience (months)	Computer Experience (months)	Product Experience (months)	Assistive Technology Needs
ID01	F	60-69	Associate	LVN/LPN	468	384	154	No
ID02	F	60-69	Doctorate	Physician	444	516	120	No
ID03	F	40-49	Associate	RN	264	300	72	No
ID04	F	30-39	Masters	ARNP	180	240	156	No
ID05	M	50-59	Doctorate	Physician	252	408	84	No
ID06	M	50-59	Bachelors	RN	444	336	54	No
ID07	F	30-39	Bachelors	RN	132	240	132	No
ID08	M	40-49	Bachelors	RN	72	360	72	No
ID09	F	50-59	Masters	ARNP	432	456	120	No
ID10	F	50-59	Doctorate	Physician	360	300	240	No

Table 1: Participants

Eleven participants matching the demographics in the Participants section were recruited and all ten participated in the usability test. (See Appendix B – Participant demographics.)

Participants were scheduled for 60-minute sessions. A minimum time interval of 15 minutes was scheduled between sessions for debrief by the administrator and data logger, and to reset systems to proper test conditions. A spreadsheet was used to keep track of the participant schedule and included key identification details for each participant.

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 IntellicureEHR. In short, this testing serves as both a means to record or benchmark current usability and identify areas for improvement.

During the usability test, participants interacted with IntellicureEHR. Each participant 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

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- 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 the Usability Metrics section of this report.

Tasks

Several tasks were constructed that would be realistic and representative of the kinds of activities a user might perform with this EHR. Tasks were selected based on the ONC CEHRT 2015 certification criteria, considering frequency of use, potential for risk to patient safety, and criticality of function. The Safety-Enhanced Design tasks for the ONC CEHRT 2015 certification criteria included:

<i>Scenario 1: Demographics</i>		
Task	Section	Risk
Access and Record Demographics (a)(5.1)	170.315(a)(5) – Demographics	Low
Change Demographics (a)(5.2)	170.315(a)(5) – Demographics	Low
Display Changed Demographics (a)(5.3)	170.315(a)(5) – Demographics	Low
<i>Scenario 2: Clinical Decision Support</i>		
Task	Section	Risk
Access and Enable CDS Interventions (a)(9.1)	170.315(a)(9) – Clinical Decision Support	High
Process a CDS Intervention(a)(9.2)	170.315(a)(9) – Clinical Decision Support	Moderate
View the Resource Information via the InfoButton Standard (a)(9.3)	170.315(a)(9) – Clinical Decision Support	Moderate
Trigger CDS Interventions with an Incorporated Transition of Care Summary (a)(9.4)	170.315(a)(9) – Clinical Decision Support	Low
Access the Reference Information for a CDS Intervention (a)(9.5)	170.315(a)(9) – Clinical Decision Support	Moderate
<i>Scenario 3: Problem List</i>		
Task	Section	Risk
Access the Active Problem List (a)(6.1)	170.315(a)(6) – Problem List	Low
Access the Historical Problem List (a)(6.2)	170.315(a)(6) – Problem List	Low
Record a New Problem (a)(6.3)	170.315(a)(6) – Problem List	Moderate
Change an Existing Problem (a)(6.4)	170.315(a)(6) – Problem List	Low
<i>Scenario 4: Implantable Device List</i>		
Task	Section	Risk
Access Implantable Device List (a)(14.1)	170.315(a)(14) – Implantable Device List	Moderate
Change an Existing Implantable Device (a)(14.2)	170.315(a)(14) – Implantable Device List	Moderate
Record a New Implantable Device (a)(14.3)	170.315(a)(14) – Implantable Device List	Moderate
<i>Scenario 5: CPOE (Computerized Physician Order Entry)</i>		
Task	Section	Risk
Access Existing Lab Orders (a)(2.1)	170.315(a)(2) – CPOE Laboratory	Low
Record a New Lab Order (a)(2.2)	170.315(a)(2) – CPOE Laboratory	High
Change a Lab Order (a)(2.3)	170.315(a)(2) – CPOE Laboratory	High
Display changed Lab Order (a)(2.4)	170.315(a)(2) – CPOE Laboratory	Moderate

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Procedure

Upon arrival in the conference call, 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 was read a request for informed consent/release and asked to give their consent verbally, which was recorded (see Appendix C – Recording Consent). A representative from the test team witnessed the participant’s verbal consent.

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 were experienced usability practitioners.

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:

- as quickly as possible making as few errors and deviations as possible
- without assistance; administrators could give immaterial guidance and clarification on tasks, but not instructions on use
- withholding questions until the end of the test

For each task, the participants were given oral directions. Task timing began once the administrator finished reading the task and said, “Begin now.” The task time was stopped once the participant indicated he or she had successfully completed the task (see Appendix D – Sample Orientation).

Following the session, the administrator gave the participant the post-test questionnaire (see Appendix F – System Usability Scale Questionnaire). Scoring is discussed below in the Data Scoring section. Participants were thanked for their time.

Participant’s demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded into a spreadsheet.

Test Location

Usability tests were conducted remotely over a conference call. The data logger started the conference call from a conference room. The test administrator joined the conference call from an office. Each participant joined the conference call from his/her location. Both the test administrator and the data logger could see the participant’s screen and listen to the audio of the session. Participants were asked to join from a location that was relatively quiet and free from distraction.

Test Environment

IntellicureEHR would typically be used in a physician’s office or community health center setting. This usability testing was conducted remotely, with participants interacting with the IntellicureEHR software over Skype for Business online conferencing software. Using remote testing allowed the participants to use the EHRUT from their normal office location. Participants were given instructions on how to access the meeting online. Once in the meeting, they were given keyboard and mouse control of the test system by the administrator. Because the EHRUT is a client-server (cloud-based) application, each

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participant was accessing the database utilized for testing using Remote Desktop Protocol (RDP) to the servers hosted at Intellicure, Inc.

IntellicureEHR staff set up the application per the product documentation describing the system setup and configuration. The application ran on a Microsoft SQL Server platform using an RDP connection. Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation.

IntellicureEHR staff set up the database used for testing (including user preferences and other configuration options). A “snapshot” and “rollback” of the database was used to ensure that the database was in the exact same configuration at the beginning of each participant’s test. Participants did not change any of the default system settings. The usability test setup provided a uniform experience to all participants.

Test Forms and Tools

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

1. Recording Consent Statement
2. Usability Protocol, including the SUS and post-test questionnaire
3. Skype for Business software

Examples of these documents can be found in the Appendices. The Usability Test Protocol was devised to be able to capture required data.

The test administrator and data logger were logged into the Skype for Business session so that each could observe the test session. The screen and audio of each participant interacting with the EHRUT were recorded using the Skype for Business recording tool. This recording provided an opportunity to replay the test for later evaluation to ensure the accuracy of timings, performance against the optimal path, etc.

Participant Instructions

The administrator read scenarios and task directions from the Usability Test Protocol to each participant. Following the procedural instructions, participants were then given 19 tasks to complete in the EHR. Tasks in the Usability Protocol are listed in Appendix E – Protocol Tasks.

Usability Metrics

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

1. Effectiveness of IntellicureEHR by measuring participant success rates and errors
2. Efficiency of IntellicureEHR by measuring the average task time and path deviations
3. Satisfaction with IntellicureEHR by measuring ease-of-use ratings

Data Scoring

The table below details how tasks were scored, errors evaluated, and the time data analyzed.

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	Rationale and Scoring
Effectiveness: Task Success	<p>Task success was determined by assigning numeric weights for various levels of task success, as follows:</p> <ul style="list-style-type: none"> • Success (without assistance) = 1.0 • Partial success = 0.5 • Failure = 0.0 <p>A task was counted as a “Success” if the participant was able to achieve the correct outcome within the time allotted on a per task basis and a ‘Partial success’ if the participant was able to achieve the correct outcome with minimal assistance. A success score for each task was calculated by averaging the scores for each task. The results are provided as a percentage. Task times were recorded for successes. Observed task times divided by the optimal time for each task were calculated as a measure of optimal efficiency. Optimal task performance time, as benchmarked by expert performance under realistic conditions, was recorded when constructing tasks. Target task times were operationally derived by multiplying a benchmarked expert performance by a factor of 2.0, allowing for some time buffer because (1) participants were not trained to expert performance, (2) some features were new, and (3) some tasks had multiple valid paths to a successful outcome. Thus, if expert, optimal performance on a task was 10 seconds then allotted task time performance was [10 * 2.0] seconds. This ratio was aggregated across tasks and reported with mean and variance scores.</p>
Effectiveness: Task Failures	<p>If the participant abandoned the task, did not reach the correct answer, performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a Failure. No task times for failed tasks or tasks that exceeded the target task time were used in calculations. The total number of errors was calculated by averaging the number of errors counted for each task. Not all deviations were counted as errors. Task failures were also expressed as the mean number of failed tasks per participant. A qualitative account of the observed errors and error types was collected.</p>
Efficiency: Task Deviations	<p>The participant’s navigation 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. Path deviations are reported on a qualitative level for use in recommendations for improvement.</p>
Efficiency: Task Time	<p>Each task was timed from when the administrator said “Begin” until the participant said “Done.” If the participant failed to say “Done,” the time was stopped when the participant ceased performing the task. Only task times for tasks that were successfully completed and tasks that were completed at or under the target time were included in the average task time analysis. Average time per task and variance measures were calculated for each task for use in the results analysis.</p>

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Satisfaction: Task Rating	Participant’s subjective impression of the ease of use of the application was measured by administering both a simple question on completion of each scenario and a post-session questionnaire. After each scenario, the participant was asked to rate “Overall, these tasks were:” on a scale of 1 (Very Difficult) to 5 (Very Easy). These data were averaged across participants. To measure participants’ confidence in and likeability of IntellicureEHR 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 F – System Usability Scale Questionnaire.
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4. Results

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.

The usability testing results for IntellicureEHR are detailed below. The results should be seen in light of the objectives and goals outlined in Study Design section. The data yielded actionable results that, when corrected, will yield a material, positive impact on user performance

Criteria 170.315(a)(2) CPOE - Laboratory

Data Analysis and Reporting

Table 3: Computerized Physician Order Entry (CPOE) -Laboratory

Task Scores	N	Task Success		Task Time (sec)		Path Deviation	Errors	
		#	Mean	(SD)	Mean	(SD)	Deviations (Observed / Optimal)	Mean
Access Existing Lab Orders	10	0.8	.421	11.2	9.063	1	0	0
Record a New Laboratory Order	10	0.7	.483	42.3	46.269	6	0	0
Change a Lab Order	10	0.4	.516	7.8	13.038	1	0	0
Display a Changed Lab Order	10	0.4	.516	8.5	4.387	0	0	0

Table 4: CPOE (Computerized Physician Order Entry) Laboratory Task Scenario

Task Scenario Ratings	Mean	(SD)
Task Group Familiarity Ratings (5 = very Familiar)	3.3	1.490
Task Group Satisfaction Ratings (5 = very easy)	3.2	1.544

Discussion of Findings

Physician/provider participants were given four CPOE laboratory tasks:

- Access Existing Lab Orders (a)(2.1)

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- Record a New Laboratory Order (a)(2.2)
- Change a Lab Order (a)(2.3)
- Display a Changed Lab Order (a)(2.4)

Effectiveness

The success scores for Accessing Existing Lab Orders was 80%, which is the most common task performed in our target market, wound care centers. Users knew how to place a new order 70% of the time, with only 40% of users able to change a lab order and subsequently view it.

Efficiency

Participants were less efficient with CPOE Labs than any other section in the Test. This is in large part due to the infrequency of use of CPOE functionality. Lab orders make up less than 0.5% of orders placed by users of Intellicure EHR.

Satisfaction

Participants had an average satisfaction rating of 3.3 out of 5 points on a Likert scale. Most participants were familiar with these tasks that they actually performed on a regular basis, and found them straightforward and easy to complete.

Major Findings

- Participants were easily able to record a new laboratory order. This task was easy to complete as the pick lists for this task were clearly defined.
- Participants had difficulty changing lab orders once they were placed, which is in alignment with the infrequency of task performance.

Areas for Improvement

Subsequent to reviewing the results of this test, we decided to redesign the lab order change procedure and created a special video series for the topic.

Criteria 170.315(a)(5) Demographics

Data Analysis and Reporting

Table 5: Demographics Task Results

Task Scores	N	Task Success		Task Time (sec)		Path Deviation	Errors	
		Mean	(SD)	Mean	(SD)		Mean	(SD)
Task	#	Mean	(SD)	Mean	(SD)	Deviations (Observed / Optimal)	Mean	(SD)
Access and Record Demographics	10	0.9	0.316	49.2	25.372	91/90	0	0
Change Demographics	10	1	0	59.7	35.752	107/100	0	0
Display Changed Demographics	10	1	0	15.1	7.400	40/40	0	0

Table 6: Demographics Task Scenario

Task Scenario Ratings	Mean	(SD)
Task Group Familiarity Ratings (5 = very Familiar)	3.8	1.126

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Task Group Satisfaction Ratings (5 = very easy)	3.2	1.147
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Discussion of Findings

Participants were given three demographics tasks:

- Access and Record Demographics (a)(5.1)
- Change Demographics (a)(5.2)
- Display Changed Demographics (a)(5.3)

Effectiveness

The success score for the Access and Record Demographics task was 90%, due to one participant requiring hints on how to complete the task. On the Change Demographics task, the success score was 100%. All participants were ultimately able to review the patient's demographics and complete the tasks. Because the workflows for these two tasks are similar, the success of the second task by those having trouble completing the first task indicates that the problem is a training issue.

Efficiency

One participant exceeded the target time for the tasks, due to unfamiliarity. All of the participants indicated that front desk personnel at their practice, rather than nurses and doctors, typically perform demographic tasks or that they were not familiar with the demographic tasks.

Satisfaction

Participants had an average satisfaction rating of 3.2 out of 5 points on a Likert scale. One participant stated, "I've never done that before and it wasn't difficult." Most participants agreed, saying if they performed these tasks daily, there would be no issue.

Major Findings

- Front desk personnel, rather than nursing staff, typically perform demographic data entry tasks.
- Several participants seemed confused by the Gender Identity selection, because gender selection is still required. Participants indicated that a better on-screen assistance would have been helpful.

Areas for Improvement

- Improve the on-screen user assistance for the required selection of patient's gender after selection of gender identity

Criteria 170.315(a)(6) Problem List

Data Analysis and Reporting

Table 7: Problem List Task Results

Task Scores	N	Task Success		Task Time (sec)		Path Deviation	Errors	
		Mean	(SD)	Mean	(SD)		Mean	(SD)
Task	#	Mean	(SD)	Mean	(SD)	Deviations (Observed / Optimal)	Mean	(SD)
Access the Active Problem List	10	0.8	.421	23.6	14.534	4	0	0
Access the Historical Problem List	10	0.7	.483	10.2	9.151	3	0	0

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Record a New Problem	10	0.6	.516	32.1	24.342	1	0	0
Change an Existing Problem	10	0.8	.422	36.5	27.403	2	0	0

Table 8: Problem List Task Scenario

Task Scenario Ratings	Mean	(SD)
Task Group Familiarity Ratings (5 = very Familiar)	3.3	1.552
Task Group Satisfaction Ratings (5 = very easy)	3.4	1.524

Discussion of Findings

Participants were given four problem list tasks:

- Access the Active Problem List (a)(6.1)
- Access the Historical Problem List (a)(6.2)
- Record a New Problem (a)(6.3)
- Change an Existing Problem (a)(6.4)

Effectiveness

The success score of Access the Active Problem List and Historical List were 80% and 70% respectively. The problem list has undergone significant redesign since our last version, so these participants had difficulty. The success scores for recording and changing a problem were similar.

Efficiency

Participants who completed the tasks, did so with either fewer steps or the same number of steps as expert users.

Satisfaction

Participants had an average satisfaction rating of 3.4 out of 5 points on a Likert scale. Most participants were familiar with these tasks and found them straightforward and easy to complete.

Major Findings

- Providers were able to access, change, and record problems without major difficulty once they were made aware of the combination of Intellicure EHR's problem and focused exam areas.

Areas for Improvement

- Additional training videos were the most requested area of improvement identified in working with patient problems

Criteria 170.315(a)(9) Clinical Decision Support

Data Analysis and Reporting

Table 9: Clinical Decision Support Task Results

Task Scores	N	Task Success		Task Time (sec)		Path Deviation	Errors	
Task	#	Mean	(SD)	Mean	(SD)	Deviations (Observed / Optimal)	Mean	(SD)

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Access and Enable CDS Interventions	10	0.8	.422	81.7	97.853	4	0	0
Process a CDS Intervention	10	0.9	.316	103.7	71.861	16	0	0
View the Resource Information via the InfoButton Standard	10	0.7	.483	57.2	55.461	6	0	0
Trigger CDS Interventions with an Incorporated Transition of Care Summary	10	0.7	.483	89.8	80.235	2	0	0
Access the Reference Information for a CDS Intervention	10	0.6	.516	19.8	19.747	2	0	0

Table 10: Clinical Decision Support Task Scenario

Task Scenario Ratings	Mean	(SD)
Task Group Familiarity Ratings (5 = very Familiar)	2.6	1.500
Task Group Satisfaction Ratings (5 = very easy)	3.2	1.882

Discussion of Findings

Participants were given five clinical decision support tasks:

- Access and Enable CDS Interventions (a)(9.1)
- Trigger a CDS Intervention and Resources for Each of the Required Elements (a)(9.2)
- View the Resource Information via the InfoButton Standard, specifically for those interventions based on the Problem List, Medication List, and Medication Allergy List (a)(9.3)
- Trigger CDS Interventions with an Incorporated Transition of Care Summary specifically based on the incorporated Problem List, Medication List, and Medication Allergy List (a)(9.4)
- Access the Reference Information for a CDS Intervention, including bibliographic citation, developer, funding source, and release or revision date (a)(9.5)

Effectiveness

The success score for the Access and Enable CDS Interventions task was 80%, indicating that providers could complete the task. Providers had more success with the Trigger a CDS Intervention task, as evidenced by the success score of 90%. The remaining tasks are in need of further examination as scores of 60 and 70% are acceptable, but in need of improvement.

Efficiency

Two out of ten participants were unable to complete the Access and Enable CDS Interventions tasks. This task group was also had the highest number of deviations of any task in this test.

Five out of ten participants were unable to complete the Process and Locate Reference Information for a CDS Intervention task within the optimal time, but all completed the task with the same number of steps as the experts.

Satisfaction

Participants had an average satisfaction rating of 3.2 out of 5 points on a Likert scale. Although most participants were unfamiliar with these tasks, many reported that they found the workflows easy to complete after having done so successfully.

Usability Test Report of Intellicure EHR

Major Findings

- Most participants were familiar with checking the patient’s clinical alerts.
- Participants had difficulty finding the reference information for the clinical alerts, although some indicated that they regularly use the reference information for patient education. See Appendix
- Configuration is typically handled on a routine basis only by administrative personnel, so clinical personnel were very unfamiliar with the tasks.

Areas for Improvement

- Improving the visibility of the reference information for clinical alerts would make the CDS features more useable.
- Providers seemed to be familiar with the patient education feature, and some providers indicated that they would like the ability to link patient education to specific clinical alerts.
- The low familiarity rating for this task scenario seems to indicate that more training on this feature for clinical staff would increase their awareness and improve its adoption.

Criteria 170.315(a)(14) Implantable Device List

Data Analysis and Reporting

Table 11: Implantable Device List Task Results

Task Scores	N	Task Success		Task Time (sec)		Path Deviation	Errors	
Task	#	Mean	(SD)	Mean	(SD)	Deviations (Observed / Optimal)	Mean	(SD)
Access Implantable Device List	10	0.9	.316	11.6	5.125	1	0	0
Change an Existing Implantable Device	10	0.9	.316	8.8	4.871	0	0	0
Record a New Implantable Device	10	0.8	.422	27.1	14.239	1	0	0

Table 12: Implantable Device List Task Scenario

Task Scenario Ratings	Mean	(SD)
Task Group Familiarity Ratings (5 = very Familiar)	3.9	1.155
Task Group Satisfaction Ratings (5 = very easy)	4.0	0.809

Discussion of Findings

Participants were given three implantable device list tasks:

- Access Implantable Device List (a)(14.1)
- Change an Existing Implantable Device (a)(14.2)
- Record a New Implantable Device (a)(14.3)

Effectiveness

The success score for each of these tasks was 100%. Participants were easily able to access, change, and record implantable devices.

Usability Test Report of Intellicure EHR

Efficiency

Although the implantable device feature was a relatively new feature for Intellicure EHR, most participants were able to complete the tasks within the optimal time for each task, as suggested by expert timings. On average, participants exceeded the optimal number of steps for the tasks due to unfamiliarity with this new feature.

Satisfaction

Participants had an average satisfaction rating of 4.0 out of 5 points on a Likert scale. Although unfamiliar with these relatively new tasks, most participants found them easy to complete.

Major Findings

- Part of the success with using this new feature may be attributable to the training provided to participants.

Areas for Improvement

- Search improvements, such as favorites or search suggestions, would improve the usability of this feature.
- Participants indicated that they would also like the ability to note implanted devices reported by the patient or referring provider, even when the device ID is not available.

Overall Results

In addition to the specific findings and areas for improvement in specific features, several overall areas for improvement recurred throughout this usability study.

Low familiarity ratings with certain functionality, along with participants' lack of awareness of the existence of some functionality, may indicate a need for training and documentation that is accessible within common workflows and provided in formats that are easily consumable by busy clinical professionals.

Another recurring feedback from participants was that workflows could better streamlined and optimized. These comments were directed mostly at the lab and decision support workflows, in particular the decision support configuration workflow. Participants were pleased with the ease of use of the implantable device workflows. This feedback identifies opportunities to make refinements to the user interface to enhance efficiency for clinicians.

Another strength that was cited by many participants was the ability to access key features from multiple locations in the software, so that they were accessible where it was logical and convenient.

The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be 74. The average SUS score for physicians/providers was 68 and for nurses/therapists was 76.25. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

Through the user-centered design and usability testing processes, opportunities to refine and enhance the user experience were identified. In particular, we performed an analysis of the Use, Tested Performance, and Error Rates in order to identify risk prone errors. Risk prone errors are those with the potential likelihood of occurrence and adverse consequences.

Usability Test Report of Intellicure EHR

Our preliminary analysis identified the following tasks as high risk:

- Access and Enable CDS Interventions
- Record a New Lab Order
- Change a Lab Order

Each of these tasks were identified as High Risk because of the lack of exposure to these features by our users. Testing confirmed that these tasks were risk prone, due to their lower success rates and deviations. Additionally, we adjusted the risk of two moderate-risk tasks to high-risk.

Pre-Test Risk Assessment	Task	Success Rate	Deviations	Post-Test Risk Assessment
High	Access and Enable CDS Interventions	80%	16	High
High	Record a New Lab Order	70%	6	High
High	Change a Lab Order	40%	1	High
Moderate	Record a New Problem	60%	1	High
Moderate	Access the Reference Information for a CDS Intervention	60%	2	High

High Risk Error Adverse Consequence Discussion

Each of these tasks have been prioritized for redesign, producing additional focused training materials, and release in upcoming release cycles. Still others will be revisited in more depth in future studies. The following is a discussion of each of these poor performing areas and how they do or do not pose adverse patient safety consequences.

Access and Enable CDS Interventions. Failure to have appropriate CDS interventions enabled has the downstream patient safety consequences of failing to alert fatigued providers about potentially identifiable and avoidable errors. Intellicure has all of the high and moderate risk CDS interventions present in our EHR enabled by default, but we will address this issue through an ongoing QA process until the task performs better after redesign and training efforts.

Record a New Lab Order and Change a Lab Order. Incorrectly ordered labs do have the adverse effect of wasting patient and provider resources as well as delay to information which has patient safety connotations. As noted earlier in the discussion, lab orders make up less than 0.5% of orders placed by users of Intellicure EHR, which we believe to be the root cause of the poor performance on these tasks by our users. We did note that enhancing our “common” list and providing a better search tool would address these issues in addition to training efforts.

Record a New Problem. This is the most common task performed in Intellicure EHR, so it was a shock to see it perform so poorly. We noted in our pre-testing assessment that it had a moderate risk due to its notable new redesign compared to Intellicure EHR version 6. Users who took the time to review the training materials on the new software performed well, so we believe that our investment in our new Training Portal, particularly the hooks directly into specific training materials from clinical documentation areas will address this issue without any product redesign.

Usability Test Report of Intellicure EHR

Access the Reference Information for a CDS Intervention. After interviewing our users post-test we don't believe that this task's poor performance in setting up a patient for adverse consequences, it still is an area which we intent do improve.

Appendix A

Sample Recruiting Screener

Participants were asked to complete an online recruiting screener prior to the test session. If they did not complete the screener prior to the test session, the test administrator asked the questions at the beginning of the session and the data logger recorded the responses.

1. Name: _____
2. Gender:
 - Male
 - Female
 - Other
3. Age:
 - 0-9
 - 10-19
 - 20-29
 - 30-39
 - 40-49
 - 50-59
 - 60-69
 - 70-79
 - 80-89
 - 90-99
 - 100+
4. Level of Education
 - No High School degree
 - High School graduate, diploma or equivalent (ex. GED)
 - Trade/technical/vocational training
 - Some college credit, no degree
 - Associate Degree
 - Bachelor's Degree
 - Master's Degree
 - Doctorate Degree (e.g., MD, DNP, DMD, PhD)
5. How long have you been working in healthcare? Please specify whether your answer is in years, months, or days. (example: 10 years) _____
6. What is your practice specialty? _____
7. How long have you been using computers? Please specify whether your answer is in years, months, or days (example: 10 years) _____
8. How long have you been using IntellicureEHR? Please specify whether your answer is in years, months, or days (example: 10 years) _____

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9. Which features do you use most frequently? Please list your top 3 (for example, orders, prescriptions, notes.)

- _____
- _____
- _____

10. On a scale of 1 to 5 with 5 being “Most familiar”, how would you rate your level of familiarity with these workflows in IntellicureEHR.

	1	2	3	4	5
a. Maintaining Problem Lists	<input type="radio"/>				
b. Reviewing and Satisfying Clinical Alerts	<input type="radio"/>				
c. Setting Up Clinical Alerts	<input type="radio"/>				
d. Ordering Lab Tests	<input type="radio"/>				
e. Entering Demographic Data	<input type="radio"/>				
f. Maintaining Implantable Device Lists	<input type="radio"/>				

11. Do you require any assistive technology to participate in this usability test?

Yes

No

Assistive technology (a)(T) is any item, piece of equipment, software program, or product system that is used to increase, maintain, or improve the functional capabilities of persons with disabilities.

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Appendix B

Participant Demographics

Below is a summary of participant demographics for this study.

Participant Gender

	n(N-10)	%
Male	3	30
Female	7	70
Other	0	0

Participant Age

Age	n(N-10)	%
30-39	2	20
40-49	2	20
50-59	4	40
60-69	2	20

Participant Education

Education	n(N-10)	%
No high school degree	0	0
High school graduate, diploma or equivalent	0	0
Trade/technical/vocational training	0	0
Some college credit, no degree	0	0
Associate degree	2	20
Bachelor's degree	3	30
Master's degree	2	20
Doctorate degree (e.g., MD, DNP, DMD, PhD)	3	30

Participants Roles

Roles	n(N-10)	%
Physician	3	30
Nurse Practitioner	2	20

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Registered Nurse	4	40
LVN/LPN	1	10

Participant Specialties

	n(N-10)	%
Wound Care	8	80
Internal Medicine	1	10
Respiratory	1	10

Participant Professional Experience

N=10	Months		Years	
Mean	304.8		25.4	
	Min	Max	Min	Max
Range	72	468	6	39

Participant Computer Experience

N=10	Months		Years	
Mean	354		29.5	
	Min	Max	Min	Max
Range	240	516	20	43

Participant Experience with IntellicureEHR

N=10	Months		Years	
Mean	120.4		10.03	
	Min	Max	Min	Max
Range	54	240	4.5	20

Appendix C

Recording Consent

Participants were asked to give a verbal consent to the statement below

Recording Consent Statement

Do you grant Intellicure, Inc. permission to record this usability test session and use this recording for internal use only for the purpose of improving the products being tested?

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Appendix D

Sample Orientation

Introduction

Thank you for agreeing to participate in this usability study. Today you will be helping us evaluate workflows pertaining to the ONC's EHR vendor certification requirements.

In a moment, I'll be asking you to complete these workflows using IntellicureEHR. I'll be taking notes and so will <note taker>.

As you go through the workflows, please keep in mind that it is IntellicureEHR under review here, not you. You may arrive at a point where you're not sure what you are supposed to do. Just take your best guess, and if you get stuck, let me know. We want to observe how you would expect to use the system if we weren't here.

Also, I want to ask you to hold your questions until the end since the workflows are being timed.

I would like to video record this session to help me later with my report. I'm going to start the recording now.

<BEGIN NOW recording the session.>

Do you grant Intellicure permission to record this usability test session and use this recording for internal use only for the purpose of improving the products being tested?

YES/NO.

Do you have any questions before we get started?

User Questionnaire

Were you able to complete the online User Questionnaire?

<If Yes – continue. If No – ask participant questions on the Questionnaire.>

Instructions

What you will be looking at today is IntellicureEHR populated with a mock patient's information. I will be asking you to perform some workflows that a user might perform with IntellicureEHR. Please keep in mind that the data may not be clinically accurate, and we understand that it may not be applicable to your specialty.

I will ask you to start when I say, "BEGIN NOW", and please tell me when you think you've completed the workflow by saying "DONE".

Appendix E

Protocol Tasks

Scenario 1: Demographics

A new patient, John Richards, is here today for his first visit. Your front desk personnel started documenting his demographic information but got pulled away before they could continue.

1. Add the following information to Mr. Richards' record before continuing with his clinical visit:
 - Date of Birth: 11/25/1970
 - Sex: Male
 - Identifies as: Male
 - Language: English
 - Sexual Orientation: Bisexual
 - Race: White, Asian
 - Ethnicity: Non-Hispanic. BEGIN NOW (a)(5.1).

Your next patient, Kara Whiteside has come in today for a follow up visit. Begin by reviewing Kara's demographic data. As you are reviewing her data with her, she reports that she gave you the wrong information on her last visit.

1. Edit the information provided by the patient.
 - Date of Birth: 10/1/1984
 - Sex: Female
 - Identifies as: Female
 - Language: French
 - Sexual orientation: Patient refused
 - Ethnicity: FrenchBEGIN NOW (a)(5.2)
2. Review the changes made to Ms. Whiteside's chart. BEGIN NOW (a)(5.3).

Those are all the demographics changes today. Please save them.

Scenario 2: Clinical Decision Support

Configuration Scenario

Before you can receive Clinical Decision Support alerts, an administrative user must use the Management Application to access and enable CDS interventions. You must add the following CDS interventions and reference resources to your users' available systems to continue.

1. Add the Diabetic Foot Ulcer Off-Loading intervention. BEGIN NOW (a)(9.1)
2. Add the Clopidogrel intervention.
3. Add the Iodine Allergy intervention.
4. Add the BMI components intervention.
5. Add the Hemoglobin A1C Screening in Patients with Diabetes intervention.

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First Clinical Decision Support Scenario:

Kara Whiteside has come in today for a follow-up visit for Hypertension, Diabetes, and a Chronic Foot Ulcer, but she also complains of Edema in her left leg. She has not had her blood pressure measured for over six months and her height and weight have not been taken today. Otherwise, your staff has updated Kara's chart, so you are ready to proceed.

1. Please open Kara's chart and review Kara's CDS Alerts. Verbally inform the patient of one of her alerts such as off-loading a diabetic foot ulcer. BEGIN NOW (a)(9.2)
2. Show me how you would review the CDS alert to find the reference information for the CDS alert Off-Load Diabetic Foot Ulcer. BEGIN NOW (a)(9.2)
3. Following the CDS recommendations that the patient needs to have a recorded BMI, add Kara's height and weight. Her height is 5'4" and her weight is 158 pounds. BEGIN NOW. (a)(9.2)

Second Clinical Decision Support Scenario

There is a feature in the EHR that electronically reconciles clinical information from an external source. Today we are going to reconcile Allergies, Medications, and Problems from the external practice named, Healthy Patients Clinic, with information in this EHR. For example, let's say Mr. Richards came to the clinic and the staff at Healthy Patients have sent you clinical information for your team to reconcile with the information in your EHR.

1. Following reconciliation, please see if there are any CDS recommendations for Mr. Richards. BEGIN NOW (a)(9.4).
2. Follow the CDS alert and order an HgbA1c for this patient. BEGIN NOW (a)(9.4).
3. There is also a CDS alert for a non-offloaded diabetic foot ulcer, follow that alert and document their offloading. BEGIN NOW (a)(9.4).

Third Clinical Decision Support Scenario

Your next patient, Fred Johnson, is a 72-year-old who has come in with an arterial ulcer and needs to be prescribed a blood thinner.

1. Please prescribe Clopidogrel 75mg once a day and be sure the medication is linked to the diagnosis. (a)(9.2)
2. Using the system, find potential patient educational material on arterial ulcers. BEGIN NOW (a)(9.3).
3. Who is the developer of this reference material? BEGIN NOW (a)(9.5)

Mr. Johnson is also taking Elavil 100 mg for pain.

1. Please look at the CDS recommendations provided for this patient and use the CDS alert to exclude the recommendation for high risk medications just for today. BEGIN NOW (a)(9.2)

Fourth Clinical Decision Support Scenario

Your next patient is 10-year-old Bobby Johnson. He is seeing you for a wound, but you have previously diagnosed him with Asthma and he has No Known allergies. The patient's mother is worried about when Grandpa comes and visits and smokes cigarettes in the house. She wants to know if that could make her child's asthma worse.

1. Using the system, find potential patient educational material on this which you could give to his mother. BEGIN NOW (a)(9.3)

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2. Who is the developer of this reference material? BEGIN NOW (a)(9.5)

Fifth Clinical Decision Support Scenario

Your last patient, Joan Smith, today is 35 years old and being seen for a checkup for her active diagnosis of Diabetes. The patient needs a CT of the pelvis with and without dye, however, the patient has an allergy to the dye. Additionally, the patient has no record of a Hemoglobin A1c in their chart.

1. Please verify the patient has a recorded allergy to Iodine, has been ordered a CT of the pelvis with and without dye, and verify there is no CDS recommendation alerting on the patient's dye allergy. BEGIN NOW. (a)(9.2)
2. Please check the CDS recommendations provided for this patient and see if there is a recommendation for obtaining a HgbA1c in patients with diabetes. BEGIN NOW. (a)(9.2)

Scenario 3: Problem List

Your staff has already updated Kara's allergies, so you are ready to proceed with her problem list.

1. Access Kara's problem list and view her active problems. BEGIN NOW (a)(6.1).
2. Now access Kara's historical problems list. BEGIN NOW (a)(6.2).
3. Record the new problem, left lower leg edema that Kara reported earlier. BEGIN NOW (a)(6.3).
4. Kara's venous stasis ulcer on the left leg has healed. Access Kara's diagnosis and update it to 'Resolved'. BEGIN NOW (a)(6.4)

Scenario 4: Implantable Device List

Kara previously had a Dermagraft in her left leg. This information has already been entered to IntellicureEHR. During her current exam, Kara also indicates she has had an Acell device implanted. You will need to review and add implantable device information for Kara in the Implantable Devices feature.

1. Access Kara's implantable device information and review the details of the Dermagraft. BEGIN NOW (a)(14.1).
2. You notice that the Body Site has not been entered. Enter 'left leg' as the Body Site for the Coronary Stent. BEGIN NOW (a)(14.2).
3. Add Kara's Acell implant to the device list. Use the Unique Device Identifier provided in the Skype for Business Chat. Add an implant date of 3/16/2017. BEGIN NOW (a)(14.3)

Scenario 5: CPOE (Computerized Physician Order Entry)

You have finished examining Kara, and you are now ready to create orders. Kara presents with a new condition today of left lower leg edema so you will order a TSH and an Albumin. You'll be adding these items in Decision Making, but please stop before you sign off the chart.

1. Open Kara's Encounter and review her existing orders. BEGIN NOW (a)(2.1)
2. Order a TSH and a Cholesterol LDL. BEGIN NOW (a)(2.2)
3. Change Kara's previously ordered Cholesterol LDL to Cholesterol HDL. BEGIN NOW (a)(2.3)
4. Confirm the changed order is displayed in the orders. BEGIN NOW (a)(2.4)

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Appendix F

System Usability Scale Questionnaire

Based on your overall experience with all the tasks, please answer the following questions.

1. I think that I would like to use this system frequently
Strongly Disagree 1 2 3 4 5 Strongly Agree
2. I found the system unnecessarily complex
Strongly Disagree 1 2 3 4 5 Strongly Agree
3. I thought that the system was easy to use
Strongly Disagree 1 2 3 4 5 Strongly Agree
4. I think that I would need the support of a technical person to be able to use this system
Strongly Disagree 1 2 3 4 5 Strongly Agree
5. I found the various functions in this system were well integrated
Strongly Disagree 1 2 3 4 5 Strongly Agree
6. I thought there was too much inconsistency in this system
Strongly Disagree 1 2 3 4 5 Strongly Agree
7. I would imagine that most people would learn to use this system very quickly
Strongly Disagree 1 2 3 4 5 Strongly Agree
8. I found the system very cumbersome to use
Strongly Disagree 1 2 3 4 5 Strongly Agree
9. I felt very confident using the system
Strongly Disagree 1 2 3 4 5 Strongly Agree
10. I needed to learn a lot of things before I could get going with this system
Strongly Disagree 1 2 3 4 5 Strongly Agree

Appendix G

References

¹ National Institute of Standards and Technology. (November 2010). NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records (NISTIR 7741). Gaithersburg, MD. nist.gov/publications/nistir-7741-nist-guideprocesses-approach-improving-usability-electronic-health-records.

² See Tullis, T & Albert, W. (2008). Measuring the User Experience. Burlington, MA: Morgan Kaufman (p.149). Broadly interpreted, scores under 60 represent systems with poor usability, scores over 80 would be considered above average.

Appendix H

Referenced Screenshots

Bibliographic Reference Citation, Intervention Developer, Funding Source, Release, and Revision dates.

The screenshot displays a sidebar on the left with a tree view under 'Outstanding Labs / Studies'. The 'Clinical Suggestions' section is expanded to show 'Off Loading' with a red circle icon, and 'Off-Load Diabetic Foot Ulcer' is selected. The main content area shows the following details:

- Title:** Off-Load Diabetic Foot Ulcer
- Summary:** Acceptable methods of offloading include crutches, walkers, wheelchairs, custom shoes, depth shoes, shoe modifications, custom inserts, custom relief orthotic walkers (CROW), diabetic boots, forefoot and heel relief shoes, and total contact casts.
- Reference:** Wound Healing Society Guidelines for the treatment of diabetic ulcers; David L. Steed MD, Christopher Attinger MD, Theodore Colaizzi, CPed CO, Mary Crossland RN, Michael Franz MD, Lawrence Harkless DPM, Andrew Johnson BS, HansMoosa MD,
- URL:** <http://onlinelibrary.wiley.com/doi/10.1111/j.1524-475X.2006.0>
- Intervention**
 - Developer:** U.S. Wound Registry; <http://www.uswoundregistry.com>
 - Funding:** U.S. Wound Registry; <http://www.uswoundregistry.com>
 - Release:** 1/1/2014
 - Revision:** 1/1/2014