ELECTRONIC HEALTH RECORD USABILITY TESTING

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

Product Name: Evolution EHR

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Report Prepared By: Adamaris Miranda

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EXECUTIVE SUMMARY

A usability test of Evolution EHR, version 3.0 a modular of EHR was conducted throughout the month of August 2018 in San Juan, PR by Infomedika, INC. The purpose of this test was to exam and validate the usability of the current user interface and provide evidence of usability in the EHR Under Test (EHRUT). During the usability test, 11 healthcare providers matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks. This study collected performance data on 37 tasks typically conducted on an EHR:

170.315(a)(1) CPOE – Medications

The user can record, change and display a medication order using a computerized provider order entry.

170.315(a)(2) CPOE – Laboratory

The user can record, change and display a laboratory order using a computerized provider order entry.

170.315(a)(3) CPOE – Diagnostic Imaging

The user can record, change and display in a diagnostic imaging order using a computerized provider order entry.

170.315(a)(4) Drug–drug, Drug–allergy Interaction Checks

When the user creates a new order using computerized provider order entry, If the medication has any interaction with the allergy reported for the patient or for the patient medication list, the system will show an alert before you complete the order.

170.315(a)(5) Demographics

Enable user to register, change and display the modification in the patient Electronic Health Record for the following: the preferred language, date of birth, birth sex, race, ethnicity, sexual orientation and gender identity. For inpatient, the system permits to write the preliminary cause of death and preliminary date of death.

170.315(a)(6) Problem List

Enable a user to record or change a problem for the patient in the problem list and display the active problems and the historical problems list.

170.315(a)(7) Medication List

Enable a user to record or change electronically a medication that the patient uses at home and can add this in the medication list. Enables access and display of active medications and the historical medications in the medication list.

170.315(a)(8) Medication Allergy List

Enable a user to record or change electronically a medication allergy that the patient has, in the medication allergy list. Enable access and display the medications allergies and the historical medications allergies in the medication allergies list.

170.315(a)(9) Clinical Decision Support

Enable a user to electronically do the clinical decision support using the configuration value that presents an alert when the vitals, allergies or laboratories have a critical value and used the info button to find the necessary information for the condition of the patient. When you use the info button in the search you can put other details like a problem with the age and a demographic detail to find the information that you need. The info buttons allow you to find information for patient education or medical references.

170.315(a) (14) Implantable Device List

Enable to record electronically an UDI and change the status. In addition, enable the access to the description, identifier and attributes of the UDI.

170.315(b)(2) Clinical Information Reconciliation and Incorporation

Enable a user to electronically reconcile the information of the medications, medications allergies and problems of the CCDA to the currently information on the patient record. Enables to do a new CCDA with the information of the patient including the reconciled data.

During the 15 minutes one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form; they were instructed that they could withdraw at any time. Participants had prior experience with the EHR. The administrator introduced the test and instructed participants to complete a series of tasks using the EHRUT. During the testing, the administrator timed the test and, along with the data logger(s) recorded user performance data on paper and electronically. The administrator did not give the participant assistance in how to complete the task.

Participant screens, head shots and audio were recorded for subsequent analysis. The following types of data were collected for each participant:

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

All participants data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire. Following is a summary of the performance and rating data collected on the Evolution EHR.

SUMATIVE USABILITY PERFORMANCE TABLE

Measures / Task	N	Task Success	Path Deviation	Task Time		Errors	Task Ratings 5=Easy
	#	Mean (SD)	Deviations (Observed/ Optimal)	Mean (SD)	Deviations (Observed/ Optimal)	Mean (SD)	Mean (SD)
(a.1) Computerized provider order entry–Medications							
o Record medications via CPOE							
o Change medications via CPOE							
o Display changed CPOE medication order							
(a.2) Computerized provider order entry–Laboratory							
o Record laboratory order via CPOE							
o Change laboratory order via CPOE							
o Display changed CPOE lab order							
(a.3) Computerized provider order entry–Diagnostic Imaging							
o Record Imaging order via CPOE							
o Change Imaging order via CPOE							
o Display changed CPOE Imaging order							
(a.4) Drug–drug, drug–allergy interaction checks for computerized provider order entry							
o Using CPOE, trigger a drug–drug interaction by entering a new medication order							

o Using CPOE, trigger a drug-allergy interaction by entering a new medication order						
o Adjust the severity level of a displayed drug-drug interaction						
(a.5) Demographics						
o Record a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only).						
o Change the patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only).						
o Display the patient's changes made in preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only).						
(a.6) Problem List						
o Record a problem to the problem list						
o Change a problem on the problem list						

o Display the active problem list							
o Display the historical problem list							
(a.7) Medication list							
o Record a medication to the medication list							
o Change a medication on the medication list							
o Display the active medication list							
o Display the historical medication list							
(a.8) Medication allergy list							
o Record a medication allergy							
o Change a medication allergy							
o Display the active medication allergy list							
o Display the historical medication allergy list							
(a.9) Clinical Decision support							
o Add a CDS intervention and/or reference resource for each of the required elements. • Problem list • Medication list • Medication Allergy List • At least one Demographic							

• Laboratory Test • Vital Signs • And a combination of at least 2 of the elements listed above.							
○ Trigger the CDS interventions/resources added using the applicable data elements from each of the required elements.							
○ View the intervention/resource information using the Info button standard for data elements in the problem list, medication list, and demographics.							
○ 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.							
○ Access the following attributes for one of the triggered CDS interventions/resources: bibliographic citation, developer, funding source, release/revision date.							
(a.14) Implantable Device List							
○ Record UDI							

o Change UDI Status							
o Access UDI, device description, identifiers, and attributes.							
(b.2) Clinical Information Reconciliation and Incorporation.							
o Incorporate a CCDA and conduct reconciliation of the medications, medication allergies, and problems in the CCDA with the information currently in the patient's record.							
o Generate a new CCDA with reconciled data.							

The results from the <u>System Usability Scale</u> scored the subjective satisfaction with the system based on performance with these tasks, to be: 64.

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

1. Major findings
2. Areas for improvement

INTRODUCTION

The EHRUT tested for this study was Evolution EHR, version 3.0, a modular EHR. Designed to present medical information to healthcare providers in ambulatory and inpatient healthcare settings, the EHRUT consists in allow providers to electronically access and record data, make support clinical decisions, and document findings at the point of 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 provide evidence of usability in the EHR Under Test (EHRUT). To this end, measures of effectiveness, efficiency and user satisfaction, such as time to perform tasks; total number of deviations; total number of errors; were captured during the usability testing.

METHOD

Participants

A total of eleven participants were tested on the EHRUT. Participants in the test were healthcare team like nurse, secretary, supervisor and coordinator of care. In addition, participants had no direct connection to the development of/or organization producing the EHRUT. Participants were not from the testing or supplier organization. Participants were given the opportunity to have the same orientation and level of training as the actual end users would have received.

The following is a table of participants by characteristics, including demographics, professional experience, computing experience and user needs for assistive technology. Participant names were replaced with Participant IDs so that an individual's data cannot be tied back to individual identities.

	Part ID	Gender	Age	Education	Occupation/role	Professional Experience
1	1	Female	35	Bachelor's Degree	Application Coordinator	168 months
2	2	Female	50	Bachelor's Degree	Nurse Supervisor	348 months
3	3	Female	32	Bachelor's Degree	EHR Coordinator	144 months
4	4	Female	39	Bachelor's Degree	Nurse Supervisor	168 months

5	5	Female	31	Bachelor's Degree	Nurse	108 months
6	6	Female	38	Technical Degree	Secretary	48 months
7	7	Female	49	Bachelor's Degree	Nurse Supervisor	312 months
8	8	Female	39	Bachelor's Degree	Nurse	228 months
9	9	Female	46	Bachelor's Degree	Nurse	84 months
10	10	Female	33	Bachelor's Degree	Nurse	24 months
11	11	Female	25	Bachelor's Degree	Nurse Coordinator	24 months

Eleven participants were recruited and 100% participated in the usability test. Participants were scheduled for 40 minutes sessions. A spreadsheet was used to keep track of the participant schedule and included each participant's demographic characteristics.

Study Design

Overall, the objective of this test was to uncover areas where the application performed well – that is, effectively, efficiently, and with satisfaction – and areas where the application failed to meet the needs of the participants. The data from this test may serve as a baseline for future tests with an updated version of the same EHR and/or comparison with other EHRs provided with the same tasks that were use. In short, this testing serves as both a means to record or benchmark current usability, but also to identify areas where improvements must be made.

During the usability test, participants interacted with Evolution EHR. Each participant used the system in the same location and was provided with the same instructions. The system was evaluated for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

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

Task

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

1. The user can record a medication via CPOE.

2. Change the medication order.

3. Display the change in the order.

4. The user can record a laboratory via CPOE.

5. Change the laboratory order.

6. Display the change in the order.

7. The user can record an imaging via CPOE.

8. Change imaging order

9. Display the change in the order.

10. Using CPOE the user triggers a drug-drug interaction by entering a new medication order.

11. Trigger a drug-allergy interaction by entering a new medication order.

12. Adjust the severity level of a displayed drug-drug interaction.

13. The user can record a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only).

14. The user can change a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only).

15. Display the change in the demographic of the patient.

16. User can record a problem to the problem list.

17. User can change a problem to the problem list.

18. Display the active problem list.

19. Display the historical problem list.

20. User can record a medication to the medication list.

21. User can change a medication to the medication list.

22. Display the active medication list.

23. Display the historical medication list.

24. User can record a medication allergy to the medication allergy list.

25. User can change a medication allergy to the medication allergy list.

26. Display the active medication allergy list.

27. Display the historical medication allergy list.

28. The user can add a clinical decision support intervention and/or reference resource for each of the required elements

      i. Problem list

      ii. Medication list

      iii. Medication Allergy List

      iv. At least one Demographic

      v. Laboratory Test

      vi. Vital Signs

      vii. And a combination of at least 2 of the elements listed above

29. User trigger the CDS interventions/resources added using the applicable data elements from each of the required elements.

30. View the intervention/resource information using the Info button standard for data elements in the problem list, medication list, and demographics.

31. 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.

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

33. User can record an UDI.

34. User can change the status of UDI.

35. User can access to the UDI device description, identifiers, and attributes.

36. User can incorporate a CCDA and conduct reconciliation of the medications, medication allergies, and problems in the CCDA with the information currently in the patient's record.

37. User can generate a new CCDA with reconciled data.

    Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users.

Procedures

    Upon arrival, participants were greeted; their identity was verified and matched with a name on the participant schedule. Participants were then assigned a participant ID. Each

participant reviewed and signed an informed consent and release form. A representative from the test team witnessed the participant's signature.

The administrator moderated the session including administering instructions and tasks. The administrator also monitored task times, obtained post-task rating data, and took notes on participant comments. A second person served as the data logger and took notes on task success, path deviations, number and type of errors, and comments.

Participants were instructed to perform the tasks:

- As quickly as possible making as few errors and deviations as possible.
- Without assistance; administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use.
- Without using a think aloud technique.

For each task, the participants were given a written copy of the task. Task timing began once the administrator finished reading the question. The task time was stopped once the participant indicated they had successfully completed the task.

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

Test location

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

Test environment

The EHRUT would be typically used in a healthcare office or facility. In this instance, the testing was conducted in a healthcare facility room destined to take the test.

For testing, a laptop pc running Windows 10, was used. Also, the participants used a mouse, keyboard and a barcode reader when interacting with the EHRUT. The Evolution EHR used 17-inch screen, 1366x968 resolution and default color settings. The application was set up by Infomedika Implementations Department according to the vendor's documentation describing the system set-up and preparation. The application itself was running on a local installation using a training

on a LAN connection. Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings.

Test forms and tools

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

1. Informed Consent
2. Moderator's Guide
3. Post-test Questionnaire

The Moderator's Guide was devised to be able to capture required data. The participant's interaction with the EHRUT was captured and recorded digitally with screen capture software running on the test machine. A video camera recorded each participant's facial expressions synced with the screen capture, and verbal comments were recorded with a microphone. The test session was electronically transmitted to a nearby observation room where the data logger observed the test session.

Participant instructions

The administrator reads the following instructions aloud to each participant:

Thank you for participating in this study. Your input is very important. Our session today will last about 40 minutes. During that time, you will use an instance of an electronic health record. I will ask you to complete a few tasks using this system and answer some questions. You should complete the tasks as quickly as possible making as few errors as possible. Please try to complete the tasks on your own following the instructions very closely. Please note that we are not testing you we are testing the system, therefore if you have difficulty all this means is that something needs to be improved in the system. I will be here in case you need specific help, but I am not able to instruct you or provide help in how to use the application.

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

Following the procedural instructions, participants were shown the EHR and as their first task, were given time 15 minutes to explore the system and make comments. Once this task was complete, the administrator gave the following instructions:

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

Participants were then given 37 tasks to complete.

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 Evolution EHR by measuring participant success rates and errors
2. Efficiency of Evolution EHR by measuring the average task time and path deviations
3. Satisfaction with Evolution EHR by measuring ease of use ratings

Data scoring

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

Measures	Rationale and Scoring
Effectiveness: Task Success	A task was counted as a "Success" if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis. The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage. Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency. Optimal task performance time, as benchmarked by expert performance under realistic conditions, is recorded when constructing tasks. Target task

	times used for task times in the Moderator's Guide must be operationally defined by taking multiple measures of optimal performance and multiplying by some factor [e.g., 1.25] that allows some time buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was [x] seconds then allotted task time performance was [x * 1.25] seconds. This ratio should be aggregated across tasks and reported with mean and variance scores.
Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as an "Failures." No task times were taken for errors. The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors. This should also be expressed as the mean number of failed tasks per participant. On a qualitative level, an enumeration of errors and error types should be collected.
Efficiency: Task Deviations	The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation. It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.
Efficiency: Task Time	Each task was timed from when the administrator said "Begin" until the participant said, "Done." If he or she failed to say "Done," the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.

Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate "Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. Common convention is that average ratings for systems judged easy to use should be 3.3 or above. To measure participants' confidence in and likeability of the Evolution EHR overall, the testing team administered the System Usability Scale (SUS) post-test questionnaire.

RESULTS

Data analysis and reporting

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above.

The usability testing results for the EHRUT are detailed below. The data should yield actionable results that, if corrected, yield material, positive impact on user performance.

Measures / Task	N	Task Success	Path Deviation	Task Time		Errors	Task Ratings 5=Easy
	#	Mean (SD)	Deviations (Observed/ Optimal)	Mean (SD)	Deviations (Observed/ Optimal)	Mean (SD)	Mean (SD)
(a.1) Computerized provider order entry–Medications							
○ Record medications via CPOE	10	70% 9.31	1.01	108.1 19.31	0.97	30% 11.15	4.8 0.42
○ Change medications via CPOE	10	30% 7.02	1.15	80.5 18.64	1.17	70% 12.41	4.2 0.79
○ Display changed CPOE medication order	10	100% 0	0	3 0	1.00	0% 0	5.0 0
(a.2) Computerized provider order entry–Laboratory							
○ Record laboratory order via CPOE	10	80% 5.67	1.00	32 12.89	0.91	20% 14.85	4.6 0.70
○ Change laboratory order via CPOE	10	30% 1.73	1.06	68.8 42.64	1.53	70% 47.44	4.4 0.84
○ Display changed CPOE lab order	10	100% 0	0	3 0	1.00	0% 0	5.0 0
(a.3) Computerized provider order entry–Diagnostic Imaging							
○ Record Imaging order via CPOE	10	50% 3.83	1.00	35.3 10.58	1.04	50% 7.53	4.3 0.82
○ Change Imaging order via CPOE	10	70% 9.06	1.13	53.8 16.79	0.90	30% 12.17	4.1 0.88
○ Display changed CPOE Imaging order	10	100% 0	0	3 0	1.00	0% 0	5.0 0

(a.4) Drug–drug, drug–allergy interaction checks for computerized provider order entry							
o Using CPOE, trigger a drug–drug interaction by entering a new medication order	10	50% 3.05	1.00	31.4 8.93	1.08	50% 8.96	4.3 0.67
o Using CPOE, trigger a drug–allergy interaction by entering a new medication order	10	50% 18.54	1.02	68.7 34.26	1.03	50% 30.29	4.4 0.70
o Adjust the severity level of a displayed drug–drug interaction	10	0% 0	1.07	49.9 14.53	2.17	100% 14.53	3.5 0.71
(a.5) Demographics							
o Record a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only).	11	27% 3.61	1.05	45.7 12.81	1.24	73% 8.10	4.3 0.48
o Change the patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only).	10	20% 0	1.25	72.7 29.89	1.45	80% 30.22	4.5 0.53
o Display the patient's changes made in preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only).	10	10% 0	1.20	11.9 15.27	3.97	90% 16.72	4.8 0.63
(a.6) Problem List							
o Record a problem to the problem list	10	0% 0	1.14	77 42.90	2.14	100% 42.90	4.8 0.42
o Change a problem on the problem list	10	30% 2.52	1.20	21.6 11.08	1.44	70% 10.98	4.8 0.42
o Display the active problem list	10	100% 0	0	3 0	1.00	0% 0	5.0 0
o Display the historical problem list	10	100% 0	0	3 0	1.00	0% 0	5.0 0

(a.7) Medication list

o Record a medication to the medication list	10	20% 3.54	1.08	65.5 16.17	1.36	80% 13.84	4.3 0.82
o Change a medication on the medication list	10	20% 0	1.07	14.7 6.43	1.63	80% 6.45	4.6 0.84
o Display the active medication list	10	100% 0	0	3 0	1.00	0% 0	5.0 0
o Display the historical medication list	10	100% 0	0	3 0	1.00	0% 0	5.0 0

(a.8) Medication allergy list

o Record a medication allergy	10	0% 0	1.03	35.1 8.90	1.53	100% 8.90	4.4 0.70
o Change a medication allergy	10	20% 1.41	1.03	19.4 7.42	1.66	80% 5.86	4.6 0.70
o Display the active medication allergy list	10	100% 0	0	3 0	1.00	0% 0	5.0 0
o Display the historical medication allergy list	10	100% 0	0	3 0	1.00	0% 0	5.0 0

(a.9) Clinical Decision support

o Add a CDS intervention and/or reference resource for each of the required elements.
 	
  o Problem list
  o Medication list
  o Medication Allergy List
  o At least one Demographic
  o Laboratory Test
  o Vital Signs
  o And a combination of at least 2 of the elements listed above.
	10	50% 12.99	1.37	156.2 48.25	1.84	50% 46.68	3.5 0.85

Task	N						
○ Trigger the CDS interventions/resources added using the applicable data elements from each of the required elements.	10	60% 11.15	1.05	32.4 9.72	1.08	40% 6.88	3.6 0.97
○ View the intervention/resource information using the Info button standard for data elements in the problem list, medication list, and demographics.	10	50% 15.22	1.93	93.3 29.68	2.92	50% 31.92	3.6 0.97
○ 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.	10	60% 36.00	2.08	129.9 33.36	1.94	40% 25.58	3.7 0.95
○ Access the following attributes for one of the triggered CDS interventions/resources: bibliographic citation, developer, funding source, release/revision date.	10	70% 18.07	1.26	64 43.55	1.68	30% 72.77	3.6 0.84
(a.14) Implantable Device List							
○ Record UDI	10	70% 13.43	1.10	82.9 88.5	1.17	30% 64.35	3.9 0.74
○ Change UDI Status	10	20% 0	1.10	13.4 9.88	3.35	80% 10.01	4.2 0.79
○ Access UDI, device description, identifiers, and attributes.	10	60% 0.89	1.05	10.7 5.62	1.78	40% 4.99	4.3 0.67
(b.2) Clinical Information Reconciliation and Incorporation.							
○ Incorporate a CCDA and conduct reconciliation of the medications, medication allergies, and problems in the CCDA with the information currently in the patient's record.	10	30% 0	1.0	44.8 9.70	1.18	70% 9.27	4.1 0.74
○ Generate a new CCDA with reconciled data.	10	80% 14.38	0.99	69.1 23.57	0.76	20% 57.27	3.9 0.99

The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be: 64. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

Discussion of the findings

All the participants who took the test had experience with Evolution EHR and were able to complete all the tasks, although not all the tasks were completed at the optimum time and with the optimal deviations. During some moments of the test each participant was observed nervous, with doubts and pensive.

Effectiveness

Although all participants completed all the tasks, we observed that when they started with the first task, only half of the participants could complete the task at the optimum time and with the optimal deviations. Once this task was completed they could more easily complete the second and third. Additionally, we saw a lot of difficulty when trying to scan the barcode to perform the device information task. Sometimes the participants performed the tasks correctly, but they became nervous when they almost completed the tasks and made mistakes or left the system when it was not necessary. In most of the participants we saw that they had doubts, but they did not ask questions. Some participants laughed, others were annoyed, nervous and confused.

Efficiency

While the participants did the tasks, we observed that they completed the tasks making very long deviations, this made them take a lot of time to complete the them and it created confusion as to how to perform it.

Satisfaction

When the test started every time, a participant finished a task we asked what number they gave to the task using the numbers 1 for more difficult and 5 for easier. We observed that the participants said 5 each time we asked, so we gave him a piece of paper and we told him to put the difficulty number of the task they did whenever they finished it. This gave us more real answers of the satisfaction of each task. When we finished the test, we gave a questionnaire to each participant to evaluate the system. We observed that almost all the participants answered that the use of the system had moderate difficulty.

Major findings

Among the biggest findings, all the participants wanted to do the task more quickly and these caused doubts because they did not read the icons that the system provided.

Areas for improvement

When we finished the test and the questionnaires to the participants we could conclude that all the participants considered that the steps to carry out the tasks should be shorter and less confusing. In addition, they indicated that the system was very slow and that it stopped at some moments. But, although this was their response, we noticed that they could have used simpler steps to complete the tasks and this would have helped them complete them. So, we thought that we need to provide a training to help use Evolution EHR. Other findings and comments from each participant can be found in the questionnaires that the participants completed.

APPENDICES

The following appendices include supporting data for this usability study. Following is a list of the appendices provided:

1. Participant demographics.
2. Non-disclosure agreement and informed consent form.
3. Moderator's guide.
4. Final questions.
5. System usability scale questionnaire.

PARTICIPANT DEMOGRAPHICS

Gender	
Men	0
Women	11
Total (participants)	11

Age Ranges	
Less than 35 years	4
Between 35 and 45 years	3
More than 45	4
Total (participants)	11

Occupation	
RN/BSN	5
Administration Staff	4
Other (Secretary)	2
Total (participants)	11

Years of Experience											
Participants	1	2	3	4	5	6	7	8	9	10	11
Year of experience Evolution EHR	6	6	3	6	6	4	3	6	3	2	2
All paper	9	20	0	9	3	0	18	13	4	0	0
Some paper, some electronic	6	9	12	6	6	4	8	6	3	2	2
All electronic	0	0	0	0	0	0	0	0	0	0	0

NON-DISCLOSURE AGREEMENT AND INFORMED CONSENT FORM

Evolution EHR Usability Study

Non-Disclosure Agreement

This agreement is entered as of August 2018 between_____, and the testing organization Infomedika, Inc. located at 181 Marginal Ave. FD Roosevelt San Juan PR 00917-3202.

The Participant acknowledges his or her voluntary participation in today's usability study, this action may bring the Participant into possession of Confidential Information. Any information the Participant acquires relating to this product during this study is confidential and property of Infomedika, Inc. and is being disclosed solely for the purposes of the Participant's partaking in today's usability study. By signing this form, the Participant acknowledges that she/he will not disclose confidential information obtained today to anyone else or any other organizations.

_____   _____

Signature   **Date**

Practice Consent

Infomedika, Inc. would like to thank you for participating in this study. The purpose of the study is to evaluate the usability of Evolution EHR (Electronic Health Record). Your participation in this study will include performing specific tasks within EHR; and completing a short survey following the study. The study should take approximately 40 minutes. The information collected during the study is for research purposes only. Your participation in this study is voluntary, so you are free to withdraw at any point during the study. When you sign this consent, you accept that you will be videotaped for research purposes. Your name and image will not be used for any other purpose. In addition, you accept that the data collected from this study may be shared with "third parties" of Infomedika, Inc. or clients. The data confidentiality is assured, and only de- identified data, like identification numbers will be used in analysis and reporting of the results.

By signing below, I agree to participate in the study.

_____   _____

Signature   **Date**

MODERATOR'S GUIDE

Evolution EHR Usability Study

Moderator's Guide	
Date	28 de Agosto de 2018
Time	9:00am a 6:00pm
Participant #	11
Location	Hospital Metropolitano San Juan, PR

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.
After all testing
• Back up all video and data files.

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

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

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

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

- Do you have any questions or concerns?

A.1: Computerized provider order entry–Medications

1. Prescribe Pepcid 20mg intravenous every 4 hours.

2. When you complete the order, change the dose for 40mg and add the duration for 5 days and cancel the previous order (reason: duplicated test).

3. When you make the modification, show the changes in the orders.

Success:

☐ Easily completed

☐ Completed with difficulty or help: *Describe*

☐ Not completed

Comments:

Task Designed Time: 3:20 min   **Finish time:**

Optimal Path: 11

☐ Correct

☐ Minor Deviations / Cycles: *Describe*

☐ Major Deviations: *Describe*

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was:

Very Difficult	Difficult	Moderate	Easy	Very Easy
1	2	3	4	5

Administrator / Notetaker Comments:

A.2: Computerized provider order entry–Laboratory

1. Add a new laboratory order for a CBC with differential.

2. When you complete the order, modify the order, add a BNP and cancel the previous order (reason: duplicated test).

3. When you finish, show the orders with the modification.

Success:

☐ Easily completed

☐ Completed with difficulty or help: *Describe*

☐ Not completed

Comments:

Task Designed Time: 2:20 min   **Finish time:**

Optimal Path: 8

☐ Correct

☐ Minor Deviations / Cycles: *Describe*

☐ Major Deviations: *Describe*

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was:

Very Difficult	Difficult	Moderate	Easy	Very Easy
1	2	3	4	5

Administrator / Notetaker Comments:

A.3: Computerized provider order entry–Diagnostic Imaging

1. Add a diagnostic imaging of CT scan abdomen (study reason: abdominal pain).

2. Add the diagnostic imaging order and add a Sono abdominal (study reason: abdominal pain).

3. Cancel the previous order (reason: error order).

4. When you finish show the change in the imaging order.

Success:

☐ Easily completed

☐ Completed with difficulty or help: *Describe*

☐ Not completed

Comments:

Task Designed Time: 2:05 min   **Finish time:**

Optimal Path: 8

☐ Correct

☐ Minor Deviations / Cycles: *Describe*

☐ Major Deviations: *Describe*

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was:

Very Difficult	Difficult	Moderate	Easy	Very Easy
1	2	3	4	5

Administrator / Notetaker Comments:

A.4: Drug-drug, drug-allergy interaction checks for CPOE

1. Trigger an interaction of drug allergy, adding the medication <u>Aspirin 81mg oral daily</u>. When you add the name of the medication, the system gives you an alert for the medication that you try to order, however, write a note (test) and make the order.

2. Then, add a new medication Plavix. The system shows you an alert of drug-drug interaction. Don't make the order.

3. Adjust the <u>severity level alert</u> and select that the system only showing you the severity interaction.

4. When done, proceed to place the order of <u>Plavix 75mg oral daily</u> , the system will not show the alert.

Success:

    ☐ Easily completed

    ☐ Completed with difficulty or help: *Describe*

    ☐ Not completed

Comments:

Task Designed Time: 3:45 min   **Finish time:**

Optimal Path: 18

    ☐ Correct

    ☐ Minor Deviations / Cycles: *Describe*

    ☐ Major Deviations: *Describe*

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was:

Very Difficult	Difficult	Moderate	Easy	Very Easy
1	2	3	4	5

Administrator / Notetaker Comments:

A.5: Demographics

1. Add or change the follow information in the electronic health record of the patient:

   - Preferred language: Spanish

   - Date of birth: 10/17/1946

   - Birth sex: Female

   - Race: White

   - Ethnicity: Hispanic

   - Sexual orientation: Bisexual

   - Gender identity: Male

2. In addition, add the follow information:

   - Preliminary cause of death: Clinical sepsis

   - Preliminary date of death: August 25, 2018

3. Display the changes in his demographic information.

Success:

☐ Easily completed

☐ Completed with difficulty or help: *Describe*

☐ Not completed

Comments:

Task Designed Time: 3:50 min   **Finish time:**

Optimal Path: 7

☐ Correct

☐ Minor Deviations / Cycles: *Describe*

☐ Major Deviations: *Describe*

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was:

Very Difficult	Difficult	Moderate	Easy	Very Easy
1	2	3	4	5

Administrator / Notetaker Comments:

A.6: Problem List

1. Add the problem Acute Chest Pain and Abdominal Pain.

2. Then, change the problem status and put the abdominal pain, inactive.

3. Show the list of active and historical problems.

Success:

☐ Easily completed

☐ Completed with difficulty or help: *Describe*

☐ Not completed

Comments:

Task Designed Time: 2:25 min   **Finish time:**

Optimal Path: 5

☐ Correct

☐ Minor Deviations / Cycles: *Describe*

☐ Major Deviations: *Describe*

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was:

Very Difficult	Difficult	Moderate	Easy	Very Easy
1	2	3	4	5

Administrator / Notetaker Comments:

A.7: Medication list

1. The patient tells you that he/she uses <u>losartan 100mg PO Daily</u> for blood pressure and that he/she doesn't use the metformin 500mg oral daily.

2. Add the medication that the patient uses to the home medication list and discontinue the medication that the patient doesn't use no more.

3. Then show the active and historical medication list.

Success:

☐ Easily completed

☐ Completed with difficulty or help: *Describe*

☐ Not completed

Comments:

Task Designed Time: 1:50 min   **Finish time:**

Optimal Path: 8

☐ Correct

☐ Minor Deviations / Cycles: *Describe*

☐ Major Deviations: *Describe*

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was:

Very Difficult	Difficult	Moderate	Easy	Very Easy
1	2	3	4	5

Administrator / Notetaker Comments:

A.8: Medication allergy list

1. When administering the prescribe medication for the patient, he/she will tell you that is allergic to the sulfa antibiotics. Add the medication to the medication allergy list.

2. Then you will see in his electronic record that she/he has an allergy to aspirin, ask the patient if she/he is allergic to aspirin, she/he will say no. Do a modification in the medication and choose inactive.

3. When you finish, show the medication in the allergy list.

Success:

☐ Easily completed

☐ Completed with difficulty or help: *Describe*

☐ Not completed

Comments:

Task Designed Time: 2:15 min   **Finish time:**

Optimal Path: 7

☐ Correct

☐ Minor Deviations / Cycles: *Describe*

☐ Major Deviations: *Describe*

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was:

Very Difficult	Difficult	Moderate	Easy	Very Easy
1	2	3	4	5

Administrator / Notetaker Comments:

A.9: Clinical Decision Support

1. Trigger a CDS intervention for the following elements, including the elements that you merged in the patient electronic record.

   - Problem list

   - Medication list

   - Medication Allergy List

   - At least one Demographic

   - Laboratory Test

   - Vital Signs

   - And a combination of at least 2 of the elements listed above

2. When you access the resources for CDS, find the following: bibliographic citation, developer, funding source, release/revision date.

3. **Success:**

   ☐ Easily completed

   ☐ Completed with difficulty or help: *Describe*

   ☐ Not completed

Comments:

Task Designed Time: 4:50   **Finish time:**

Optimal Path: 10

   ☐ Correct

   ☐ Minor Deviations / Cycles: *Describe*

   ☐ Major Deviations: *Describe*

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was:

Very Difficult	Difficult	Moderate	Easy	Very Easy
1	2	3	4	5

Administrator / Notetaker Comments:

A.14: Implantable Device List

1. Add the UDI information of the patient to the electronic record.

UDI: (01)10884521062856(11)141231(17)150707(10)A213B1(21)1234

(01)10884521062856(11)141231

(17)150707(10)A213B1(21)1234

2. When you add the UDI, change the status to inactive.
3. Access the implant data to see the information of the device.

Success:

☐ Easily completed

☐ Completed with difficulty or help: *Describe*

☐ Not completed

Comments:

Task Designed Time: 2:00 min   **Finish time:**

Optimal Path: 6

☐ Correct

☐ Minor Deviations / Cycles: *Describe*

☐ Major Deviations: *Describe*

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was:

Very Difficult	Difficult	Moderate	Easy	Very Easy
1	2	3	4	5

Administrator / Notetaker Comments:

B.2: Clinical Information Reconciliation and Incorporation

1. Make a reconciliation of the received information with the current electronic record of the patient.

   - Medication: Tylenol and Ceftriaxone

   - Allergies: Penicillin

   - Problems: Fever and Overweight

2. When you finish, make a new CCDA (account summary) of the patient information with the reconciled data.

Success:

☐ Easily completed

☐ Completed with difficulty or help: *Describe*

☐ Not completed

Comments:

Task Designed Time: 2:10 min   **Finish time:**

Optimal Path: 11

☐ Correct

☐ Minor Deviations / Cycles: *Describe*

☐ Major Deviations: *Describe*

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was:

Very Difficult	Difficult	Moderate	Easy	Very Easy
1	2	3	4	5

Administrator / Notetaker Comments:

FINAL QUESTIONS

1. What was your overall impression of the Evolution EHR?

   ☐ Very easy

   ☐ Easy

   ☐ Moderate

   ☒ Difficult

   ☐ Very difficult

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

   _____

3. What aspects of the system did you like least?

   _____

4. Were there any features that you were surprised to see? If the answer is yes, which one?

   ☐ Yes, _____.

   ☐ No

5. Do you think that the Evolution EHR need any features that you expected to encounter but you did not see? If the answer is yes, which one?

   ☐ Yes, _____.

   ☐ No

6. Would you recommend this system to your colleagues?

   ☐ Strongly agree

   ☐ Agree

   ☐ Maybe

   ☐ Disagree

   ☐ Strongly Disagree

7. In general aspect, what do you think about the Evolution EHR.

   _____

   _____

SYSTEM USABILITY SCALE QUESTIONNAIRE

		Strongly Disagree				Strongly Agree

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

    1   2   3   4   5

2. I found the system unnecessarily complex.

    1   2   3   4   5

3. I thought the system was easy to use.

    1   2   3   4   5

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

    1   2   3   4   5

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

    1   2   3   4   5

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

    1   2   3   4   5

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

    1   2   3   4   5

8. I found the system very cumbersome to use.

    1   2   3   4   5

9. I felt very confident using the system.

    1   2   3   4   5

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

    1   2   3   4   5