Safety-enhanced Design

Edaris Health Urgichart

Version 2.0

170.315 (a)(1) CPOE Medication Order
170.315 (a)(2) Laboratory
170.315 (a)(3) Diagnostic Imaging
170.315 (a)(4) Drug-Drug, Drug-Allergy Interactions
170.315 (a)(5) Demographics
170.315 (a)(6) Problem List
170.315 (a)(7) Medication List
170.315 (a)(8) Medication Allergy List
170.315 (a)(9) CPOE Clinical Decision Support
170.315 (a)(14) Implantable Device List
170.315 (b)(2) Clinical Information Reconciliation and Incorporation
170.315 (b)(3) Electronic Prescribing

Report content based on NISTR 7742, Customized Common Industry Format Template for Electronic Health Record Usability Testing.

Feature Tested: Edaris Health's Urgichart Version 2.0

Date of Usability Testing: 9/1/2017 – 9/4/2017

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1 EXECUTIVE SUMMARY

Usability tests of Edaris Health's Urgichart Version 2.0 Electronic Healthcare Records software were conducted on September 1st, 2017 thru September 4th, 2017 at various locations through Phoenix, AZ with one participant joining by web conference. The purpose of these tests was to validate the usability of the participant interface being developed and released in Version 2.0 of the Urgichart software, and provide evidence of usability in the EHR Under Test (EHRUT). During the usability tests, ten healthcare professionals matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative, tasks.

This study collected performance data on twelve* measures for which certification was being sought for by demonstration. The following measures were tested during the usability testing event:

- 170.315 (a)(1) CPOE Medication Order
- 170.315 (a)(2) CPOE Laboratory Order
- 170.315 (a)(3) CPOE Diagnostic Imaging
- 170.315 (a)(4) Drug-Drug, Drug-Allergy Interactions
- 170.315 (a)(5) Demographics
- 170.315 (a)(6) Problem List
- 170.315 (a)(7) Medication List
- 170.315 (a)(8) Medication Allergy List
- 170.315 (a)(9) CPOE Clinical Decision Support
- 170.315 (a)(14) Implantable Device List
- 170.315 (b)(2) Clinical Information Reconciliation and Incorporation
- 170.315 (b)(3) Electronic Prescribing

During the 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 from participation at any time. None of the participants had any prior exposure to Urgichart. The administrator introduced the test, and instructed participants to complete a series of tasks (given one at a time) using the EHRUT. During the testing, the administrator timed the test, kept count of mouse clicks and monitored for alternate functional paths. The administrator gave the participants minor assistance in how to complete the task if needed, and such guidance was documented on the note taker tracking sheet.

Prior to testing, the test administrator reviewed the clinical workflow requirements that were being executed with the EHR and spent time with each candidate navigating similar tasks in the EHR to provide the candidate an introduction to the Urgichart application.

Participant feedback was recorded for subsequent review and have been provided to the product development department. Each participant was given the opportunity to record their

perception of ease of use and overall effectiveness in meeting clinical workflow requirements on each feature tested. Participants also completed a System Usability Survey (SUS) at the end of their testing experience.

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a posttest questionnaire and were compensated with a $25 gift card for their time.

The following types of data were collected for each participant:

- Number of tasks successfully completed within the allotted time
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations
- Participant's satisfaction ratings of the system

The UCD process used was based on NISTIR 7741 and various recommended metrics were used to evaluate the usability of Urgichart. Examples set forth in the 'NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records' were used to evaluate the usability of the Electronic Health Record Under Test (EHRUT.)

Measure Task	N	Task Success	Path Deviation	Task Time		Errors	Task Ratings 5=Easy
	# of Task	Mean (SD)	Deviations (Observed /Optimal)	Mean (SD)	Deviations (Observed/ Optimal)l	Mean (SD)	Mean (SD)
CPOE Medication Order	10	0.9 (0.3)	1.13	89 (26.9)	0.95	0.1(0.3)	4.2 (0.6)
Medication List	10	0.95 (.16)	1.0	148 (60.8)	0.70	0.1(0.3)	4.4 (0.5)
Electronic Prescribing	10	0.50 (.52)	1.2	116 (70.0)	0.91	0.0 (0.0)	3.9 (0.7)
CPOE Laboratory Order	10	1.0 (0.0)	1.2	102 (44.8)	0.87	0.0 (0.0)	3.9 (0.8)
Drug-drug, Drug-allergy Interaction Check	10	1.0 (0.0)	1.2	88 (45)	0.92	0.0 (0.0)	4.3 (0.8)

Medication Allergy List	10	0.9 (0.1)	1.0	147 (23.9)	0.66	0.1 (0.3)	4.5 (0.7)
Problem List	10	1.0 (0.0)	1.2	64.0 (52)	0.62	0.0 (0.0)	4.6 (0.5)
CPOE Diagnostic Imaging Order	10	1.0 (0.0)	1.3	89 (26.9)	0.70	0.0 (0.0)	4.3 (0.8)
Clinical Information Reconciliation and Incorporation	10	1.0 (0.0)	1.1	99 (23.7)	0.69	0.0 (0.0)	4.1 (1.2)
Demographics	10	1.0 (0.0)	1.1	185 (80)	1.10	0.2(0.6)	3.9 (1.3)
Implantable Device List	10	1.0 (0.0)	1.3	150 (20.3)	0.90	0.0 (0.0)	4.4 (.7)
Clinical Decision Support	10	1.0 (0.0)	1.1	52.1 (17.9)	1.33	0.0 (0.0)	3.9 (1.3)

An explanation of the summary table 1 is as follows:

- Number of tasks is a sum of the total number of tasks testing participants were asked to complete for the measure being tested.
- The success rate was calculated by taking the number of tasks completed successfully by all participants and dividing it by the total number of tasks assigned to all participants.
- Path deviation rate was calculated by the total number of path deviations observed divided by the total number of tasks completed by all test participants.
- Errors were defined as variances to tasks that the participant introduced, such as clicking on the wrong field or not selecting an item as specified in the script, and the measure failed
- Average measure time is the sum of the average times for each bank of tasks completed.
- Task efficiency is the participant's perception on how easy the task was to complete (time and navigation being considered)

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

- Major finding:

- Identifying the Order Entry module was a consistent issue as it not located near the other modules (i.e., Medication, Allergies, Discharge, etc.)
- Within the Order Entry module, participants consistently tried to click on the word 'labs' rather than search for desired labs order in the search field.
- Modifying, editing and changing orders brought confusion as the "Edit" button (pencil icon) does not edit medications that are being prescribed, they need to be deleted and reentered. If a user attempts to edit the order with the pencil, it requires the user to go back to the discharge menu and re-enter the "Add/Edit Rx"
- Many of the items that required change or addition needed to be "added to the list", this led to some confusion due to the location and lack of attention brought to such a significant button. The result was missed orders and medications that required the user to reenter the information.
- The most amount of errors occurred during the search for existing patients; the users found the searching functionality to be difficult and confusing at times
- Displaying order details was found to be intuitive and simple.
- Importing medications and allergies was received very well with users that are familiar with having to enter data from patients.
- The Clinical Decision Support rule that was tested for identifying the correct patient to eliminate human error was thought to be very helpful and did not contribute to "alert fatigue"

- Areas for improvement:

- Design more visible buttons for storing, saving or adding information
- Enlarge and highlight the module access points; needs to be more distinguished
- Remove the separation between the "favorite" section and "search" function when looking to order labs or images.
- Allow 'patient look-up' by any part of patient's name
- Allow users to press "enter" when completing a search

2 INTRODUCTION

The EHRUT tested for this study was the Edaris Health Urgichart CPOE Medication Order, Medication List, Electronic Prescribing, CPOE Laboratory Order, Drug-drug, Drug-allergy Interaction Check, Medication Allergy List, Problem List, CPOE Diagnostic Imaging Order, Clinical Information Reconciliation and Incorporation, Demographics, Implantable Device List, Clinical Decision Support features for Version 2.0. Designed to present medical information to healthcare providers in acute care and family medicine settings, the EHRUT consists of an electronic chart with computerized provider order entry capabilities. The usability testing

attempted to represent realistic exercises and conditions and used scripts and content as defined in the ONC 2015 Edition EHR Certification Scripts.

The purpose of this study was to test and validate the usability of the current participant interface and workflows, and provide evidence of usability in the EHR Under Test (EHRUT). To this end, measures of efficiency (pathway deviations, time to complete) and participant satisfaction, such as perceived ease of use, and feature navigation were captured during the usability testing.

3 METHOD

3.1 PARTICIPANTS

A total of ten participants were tested on the EHRUT. Participants in the test were familiar with patient care workflows and ranged in clinical experience. Participants were recruited by an Edaris Health employee based on clinical background and did not have any responsibilities or rolls in the development of the Urgichart product. Participants were given the opportunity to have the same orientation and level of training as the actual end participants would receive. For the test purposes, end-participant characteristics were identified and translated into a participant persona which was used to screen potential participants. This included clinicians with a strong understanding of the medication management process, which included management of orders, documentation of medications and allergies, documenting problems, working with clinical decision support, and performing clinical information reconciliation.

Table 2 below, summarizes participants by characteristics, including demographics, professional experience and computing experience. Recruited participants had a mix of backgrounds and demographic characteristics consistent with the user population found in an acute care and family medicine settings. Participant names were replaced with ID numbers so that an individual's data cannot be tied back to the participant.

Participants were scheduled for one hour sessions, which included time for debrief by the administrator. A spreadsheet was used to keep track of the participant schedule.

Table 2

Id	Gender	Credentials	Setting	Years of Professional Experience	Years of Personal or Professional Computer Use
ID01	M	MD	ED	20	10
ID02	F	PA-C	Primary Care	2	10+
ID03	F	PA-C	Primary Care	9	25

ID04	F	PA-C	Urgent Care	14	30
ID05	F	Medical Assistant	Family Medicine	5	10
ID06	F	PA-C	Primary Care	2	25
ID07	F	RN	Med-Surg	8	10
ID08	M	BS	Clinical Support	8	26
ID09	M	DDS	General Dentistry	17	30
ID10	M	BS	PGY 4 Dental Student	0	10

3.2 STUDY DESIGN

Overall, the objective of this test was to uncover areas where the application performed well – that is, efficiency (pathway deviations, time to complete) and participant satisfaction, such as perceived ease of use– 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 new versions of the same EHR and/or comparison with other EHRs provided the same tasks are used. In short, this testing serves as both a means to record or benchmark current usability, but also to identify areas where improvements must be made.

During the usability test, participants interacted with the Edaris Health Urgichart EHR software. Individual testing events were held from September 1st, 2017 thru September 4th, 2017 at various locations in Phoenix, AZ. One of the ten participants took part via a Web meeting. The same instructions were provided for all participants. A participant test guide was used to provide task instructions, record task results and record participant feedback.

Each feature was evaluated for efficiency, effectiveness, and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within the allotted time
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the EHR software

3.3 TASKS

Tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR in the acute care and family medicine settings.

3.3 - a.1 CPOE Medication Order

Participants were assigned CPOE Medication Order tasks as follows:

1. Ordering medications
2. Modifying medications orders
3. Accessing medication orders

3.3 – a.2 CPOE Laboratory Order

1. Ordering laboratory tests
2. Modifying laboratory orders
3. Accessing laboratory orders

3.3 – a.3 CPOE Diagnostic Imaging

1. Ordering diagnostic imaging
2. Modifying imaging orders
3. Accessing imaging orders

3.3 – a.4 Drug-Drug, Drug-Allergy Interactions

1. Manage allergy severity settings
2. Evaluate DD/DA alert when triggered during order management

3.3 – a.5 Demographics

1. Create new patient chart
2. Access patient's demographic data
3. Modify patient's demographic data
4. Record new patient demographic data

3.3 – a.6 Problem List

1. Record new problem
2. Change existing problem
3. Access problem list

3.3 – a.7 Medication List

1. Record active medication
2. Change active medication
3. Access active medication list

3.3 – a.8 Medication Allergy List

1. Record new allergy
2. Change existing allergy
3. Access allergy list

3.3 – a.9 CPOE Clinical Decision Support

1. Evaluate Clinical Decision Support related to prescribing NSAID when patient has active NSAID allergy
2. Evaluate Clinical Decision Support related to patient demographic (Date of Birth) when triggered during selecting the a patient with the same name

3.3 – a.14 Implantable Device List

1. Record Unique Device Identifiers associated with patient's Implantable Device

3.3 – b.2 Clinical Information Reconciliation and Incorporation
Participants were assigned one of the following Clinical Information Reconciliation measure tasks to follow:

1. Reconcile charted home medications and medications imported from a CCDA.
2. Add reconcile medications to the patient's active medications using order management.
3. Reconcile charted patient allergies with allergies imported from a CCDA.

3.3 – b.3 Electronic Prescribing

1. Create new prescriptions
2. Edit prescription
3. Cancel prescription

Tasks were developed based on their frequency of use, criticality of function, and those that introduce risk into the care process.

3.4 PROCEDURES

Upon arrival, participants were greeted and their identity was verified. Participants signed sign-in register and were assigned a participant ID. Each participant reviewed and signed an informed consent and release form. The testing administrator witnessed the participant's signature.

To ensure that the test ran smoothly, individual instructions were given concerning the collection of measurement data.

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. The administrator tracked time, errors, path deviations, and comments.

Following the session, the administrator gave the participant the post-test questionnaire.

3.5 TEST LOCATION

The test facilities included a waiting area and a quiet testing room with a table and computer with an information and instruction guide with a list of tasks to be executed.

3.6 TEST ENVIRONMENT

To ensure that the environment was comfortable for participants, noise levels were kept to a minimum with the ambient temperature within a normal range as expected in the typical physician office or community health center environment. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants. The database used for testing was reset between participants to ensure that settings were the same at the start of each participants set.

3.7 TEST FORMS AND TOOLS

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

1. Informed Consent
2. Non-Disclosure
3. Acknowledgement of Receipt
4. Demographic Sheet
5. System Usability Survey
6. Task Usability Scale Survey
7. Moderator's Guide
8. Participant's Guide
9. Stopwatch
10. Go To Meeting for recording of sessions

3.8 PARTICIPANT INSTRUCTIONS

Participants were instructed to perform the tasks (see specific instructions below):

- As quickly as possible making as few errors and deviations as possible.
- Perform each task without assistance.

Administrators were allowed to give immaterial guidance and clarification on tasks, with limited instructions on use.

For each task, the participants were given a written copy of the task. Task timing began once the administrator finished reviewing the test script and ensured the participant understood the test objectives. The task time was stopped once the participant indicated they had successfully completed the task. Scoring is discussed below in Section 3.9

Following the session, the administrator gave the participant the System Usability Survey.

Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and system usability survey were recorded into a spreadsheet.

3.9 USABILITY METRICS
Usability Metrics

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, was 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 a factor 2 that allows some time buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was 60 seconds then allotted task time performance was [60 * 2] seconds. This ratio was 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 for failed tasks or tasks that exceeded the target task time were used in calculations.
Efficiency:	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

Task Deviations	menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. The number of mouse clicks was collected and the standard deviation calculated. Path deviations are reported on a qualitative level for use in recommendations for improvement.
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 for efficiency and effectiveness were measured by administering a simple post-task question as well as a post- session questionnaire. After each task, the participant was asked to rate efficiency based upon number of mouse clicks, navigation and time it took to complete the task: "Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. After each task, the participant was asked to rate effectiveness based upon meeting clinical requirements: "Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. At the end of each session the participant was asked to complete the Software Usability Survey. To measure participants' confidence in and likeability of the Urgichart system 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.

4 RESULTS
4.1 DATA ANALYSIS AND REPORTING

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

Measure Task	N	Task Success	Path Deviation	Task Time	Errors	Task Ratings 5=Easy

	# of Task	Mean (SD)	Deviations (Observed /Optimal)	Mean (SD)	Deviations (Observed/ Optimal)l	Mean (SD)	Mean (SD)
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Clinical Decision Support	10	1.0 (0.0)	1.1	52.1 (17.9)	1.33	0.0 (0.0)	3.9 (1.3)

The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data yields actionable results that, if corrected, yield material, positive impact on participant performance and improved usability of EHRUT.

4.2 DISCUSSION OF THE FINDINGS

SATISFACTION

All of the users were provided a system usability scale test with the intent to measure their overall feelings toward the Urgichart product. An important step in the process of executing this test was to accurately measure the end users' satisfaction in handling and executing the requested tasks. While some participants had some difficulty—as expected when using a brand new system—the overwhelming reaction was in favor of satisfaction when using Urgicart 2.0. The vast majority of the participants were not on either extreme (i.e., 1 or 5) of the scale and it was reported, when asked if the user felt "very" confident using the system, users scored Urgichart 2.0 with an average score of 3.85.

MAJOR FINDINGS

4.2 – a.1 CPOE (Medication Order, Laboratory Order, Diagnostic Imaging, Clinical Decision Support)

Edaris Health elected to combine the major findings with the CPOEs (Medication Order, Lab Order, Diagnostic Imaging Order) as well as the Clinical Decision Support task given the similarity in task demands and the menus associated with the search, addition, editing and storing the orders. It was found that the tests for these measure all had similar findings and/or deviations when tracking the participants efforts. The main theme was the location within the Order Entry module where a user would search for an order that was not previously saved to a favorites list. The location of this search bar is just below where most all users were looking, but, spatially, it appears as though the Search is in another section. Despite the issues with identifying the Search, all Users were very pleased with the ease of adding and editing orders with the simple check boxes that the Urgichart 2.0 application utilizes.

This was particularly apparent when we had a user accidentally add an incorrect order (LT vs. RT), the user, without any knowledge of the system was able to remove the incorrect order and add the correct imaging order. This participant did not receive any verbal instruction once the error was made as the user realized—immediately—and intuitively went on to make the necessary corrections to follow the task script.

The Clinical Decision Support was received well (scored 4.08 on a scale of 1-5) with the exception of one participant scoring a 1. Six users selecting this feature as a 5 on the scale, which led this tester to think that the user misread the question as it was not in line with the majority of their test scores.

4.2 – a.4 Drug – Drug/Drug – Allergy Interaction Checks

One hundred percent of the assigned tasks were completed successfully without errors. The Drug-Drug/Drug-Allergy scripts produced one deviations from the preferred path of completion.

4.2 – a.5 Demographics

All tasks were successfully completed; however, there were several path deviations, which most stemmed from the data entry portion of the demographics section. One user in particular had a total of 4 deviations when attempting to enter the new patient's information. As I'll discuss in the "areas for Improvement section" the Patient Lookup requirements are not listed clearly and resulted in deviations.

The background information that needed to added was handled especially well—once the patient was successfully created.

4.2 – a.6 Problem List

Every user completed the task. The only deviations that occurred, which accounted for all 5 deviations, was the necessity to include an onset date. The system alerted the users and a date was simply entered after the advisory popup. All participants were able to self-correct the issue without further guidance.

4.2 – a.7 Medication List

The medication list saw the most variance of any task resulting in two failed attempts to add medications properly. Both of the users that failed the task entered the data in the wrong module. The error occurred when they added the medication—as described—but in the wrong area of the application. Both users did not exit the "Add/Edit Rx" section in the Discharge module, as instructed; instead, they attempted to add the requested medications to the new prescription versus adding the medication in the patients *existing* medications.

4.2 – a.8 Medication Allergy List

This task did receive one failure as the user completely skipped the page where the allergies were listed. This was only realized after the test was conducted when reviewing the video recorded session. This tester missed the user's omission during the testing session.

This task only saw one deviation which did not actually impact the outcome. The user entered/edited the medication allergies in reverse order that was written in the instructions

4.2 – a.14 Implantable Device List

The task was very simple and straightforward from a system standpoint. The interesting part when reviewing the scores, participants had mixed feelings. This stemmed for the displeasure that the users had to manually enter the Unique Device ID (UDI) which is very long, non-sequential string on numbers, characters, and letters. This was a time consuming task and generally irritated the users.

4.2 – b.2 Clinical Information Reconciliation and Incorporation

Medication and allergy reconciliation posed no problems for the participants and one hundred percent of the assigned task were complete successfully, unfortunately there were three path deviations, which, again, stemmed from the issue with the Patient Lookup functionality, not with the actual task of reconciling the clinical information

4.2 – a.3 Electronic Prescribing

All participants were able to successfully send eRx based on the information provided. There were 4 deviations during the process that all occurred during the medication change stage before sending the prescription. All deviations clicked the edit button (Pencil Icon) instead of deleting the order (which keep the med listed, just crossed out).

The process of sending the eRx was handled very successfully and was scored as easy to use when evaluating the actual process of submitting a new prescription electronically from the Urgichart 2.0 application.

In the example given, the participants were accessing a patient that already had the designated pharmacy provided. The tester specifically left out the step of adding a pharmacy to focus solely on eRx functionality.

AREAS FOR IMPROVEMENT

4.2 – a.1 CPOE

- The process for searching all orders (labs, imaging) are located in a location that created confusion with the users, if the search bar was highlighted or raised to be located closer to the Labs, Imaging headers.

- The process for canceling an ancillary order caused confusion as the request was not always placed in the verification tray.
- When searching frequencies and routes, the pick list entry may be far down in the list. Although it is highlighted, participants often did not see the selected item. Participants were expecting the selection to be presented in the search window.
- The Store/Print button was a bit of a challenge to locate for users as it is not located in the same location as other menus in the application.

4.2 – a.4 Drug – Drug/Drug – Allergy Interaction Checks

- Participants appreciated the ability to allow for different severity levels in CPOE than those set in the pharmacy system.
- The alert banner on the interaction check could be larger to ensure the clinician sees the interaction while entering the data to prevent them from continuing to enter information.

4.2 – a.5 Demographics

- The Phone number field needs to either note that dashes are required for submission, or automatically fill in the dashes when entering the required phone number field.
- There were issues with participants finding the “Background” module. There was feedback that suggested that it should be located underneath the Social History module.

4.2 – a.6 Problem List

- Add stars to necessary fields. The main issue that contributed to deviations was the necessity to include an onset date to add the problem to the list, but the field shows no indication that it is a mandatory field, despite the users being told to populate the Onset field in the instructions.

4.2 – a.7 Medication List

- Add/highlight to “Add to List” button—this is a key step to ensure the medication is properly added, without “adding to the list”, the medications will not add to the patients record.

4.2 – a.8 Medication Allergy List

- Editing an existing allergy brought some confusion because when the user selected the established allergy from the active menu, the results auto-populate in the fields, but the users were not always aware of the feature and pressed the "edit" button several times.

4.2 – a.14 Implantable Device List

- Have the UDI in an area that can be copied/pasted into the Urgichart 2.0 application. It should be noted that the system allows the field to paste outside text, but the participants in this test were asked to manually enter the long Unique Device ID

4.2 – b.2 Clinical Information Reconciliation and Incorporation

- Highlight/ add emphasis to the import buttons that reconcile the clinical information.
- Participants were unsure of the process to accept and merge pending data into a single list; requests cues be provided.

FORERUN
CLINICAL INFORMATION SYSTEMS FOR THE ED

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Quality Management Systems (g.4) Attestation

Forerun Systems
Urgichart Version 1.0

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Forerun uses a modify ISO/IEC 12207:2008 Quality Management System.

It covers all the criteria for which we are applying including:

170.315.a.1 Computerized Provider Order Entry (CPOE) - Medications
170.315.a.2 Computerized Provider Order Entry (CPOE) - Laboratory
170.315.a.3 Computerized Provider Order Entry (CPOE) – Diagnostic Imaging
170.315.a.4 Drug-drug, Drug-allergy Interaction Checks for CPOE
170.315.a.5: Demographics
170.315.a.6 Problem List
170.315.a.8 Medication Allergy List
170.315.a.12 Family Health History
170.315.a.14 Implantable Device List

1. Problem identification or enhancement request entered into Bugzilla by acquirer (stakeholder)
2. Report sent to request for approval queue (agreement and contract by customer)
3. Approved report prioritized by development manager
4. Report assigned to developer according to priority
5. Developer fixes / modifies code according to report
6. Developer works with author to gain insight and solicit feedback
7. At completion, quality assurance tests and signs off on the report
8. Quality assurance reviews and verifies the finished product with reporter to meet specification
9. Account manager shows change to customer to validate feature and solicit feedback
10. Product/feature release is ready to be deployed.

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Short Description:

The Quality Management System utilized at Forerun follows the software development life cycle:

Design Evolution ~> Requirements Analysis ~> Design / Development ~> Integration & Test ~> Implementation / Review.

When problems or enhancements are identified by a customer or internal user, the software is tested to reproduce the issue. Testing steps and supporting information are submitted into the Bugzilla bug tracking system with the bug report. The bug report is sent to a development program manager for approval. The bug report is prioritized and placed into the queue. The report is assigned to a developer according to the priority. The developer fixes or modifies the code according to the report. The developer tests the fix implemented. The developer works with the author to demonstrate the fix, gain insight and solicit feedback. Quality assurance tests the fix included in an internal mock production environment. Quality assurance signs off on the fix. Quality assurance shows the finished product to the author. The account manager shows the change / fix to the customer to solicit feedback.

[Signature]
[Signature Block of Authorized Senior Company Representative]
[Date signed]

200 West St.
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Forerun Systems
Urgichart Version 1.0

Carolyn Doucette
Director of Urgichart
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For public release:
Forerun Systems attests that the usability standard/process and usability report submitted for the certification of Urgichart Version 1.0 is accurate and complete per the requirements of the ONC criterion 170.315(g)(3).

[Signature]
[Signature Block of Authorized Senior Company Representative]
[Date signed]

Appendix A: Attestation Template for Approach #1

Privacy and Security Certification Documentation

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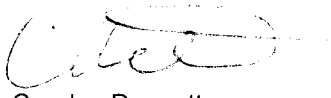
Urgichart only needs to be tested once per each applicable privacy and security criteria as the privacy and security capabilities apply to the full scope of capabilities included in the requested testing and certification, except for the following:

- Any health IT system presented for certification to § 170.315(e)(1) must be separately tested to § 170.315(d)(9) [Per the ONC Final Rule].
- Any health IT system presented for certification to § 170.315(e)(2) must be separately tested to § 170.315(d)(9) [Per the ONC Final Rule].

I hereby attest that all above statements are true, as an authorized signing authority on behalf of my organization.



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Auditable Events (d.2) Attestation Template

Privacy and Security Certification Documentation

1. **Does the health IT module audit logging capability monitor each of the required actions for all instances of electronic health information utilized by the health IT module in accordance with the specified standard ASTM E2147-01?** [IN170.315(d)(2)(i)(A)]

   Yes. *Confirm via statement.*

   Addition: Yes, logging capability
   Deletion: Yes, logging capability
   Changes: Yes, logging capability
   Queries: Yes, logging capability
   Print: Yes, logging capability
   Copy: ***N/A****, The application does not allow copy option*
   Changes to User Privileges: YES, logging capability
   Access to patient information, including emergency access events: Yes, logging capability

2. **If applicable, and if the health IT module allows it be disabled, is the default state for audit log and audit log status recording enabled by default?**
   [IN170.315 (d)(2)(i)(B) and (ii)]

   No. *Confirm that the health IT module does not permit the audit log or audit log status to be disabled.*

3. **If applicable, and if the health IT module allows it to be disabled, is the encryption of electronic health information on end-user devices enabled by default?** [IN170.315(d)(2)(i)(C) and (ii)]

   No. *Confirm that the health IT module does not store electronic health information on end-user devices.*

4. **Describe the method(s) through which the audit log protects the following from being changed, overwritten, or deleted by the health IT module.** [IN170.315(d)(2)(iv)]

   No. Confirm that the health IT module does not changed, overwritten, or deleted by the health IT module.

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5. **Describe the method(s) through which the health IT module is capable of detecting whether the audit log(s) have been altered. Note: This type of alteration would be from outside the health IT module (e.g., hacking, manual tampering, and other software besides the health IT module).** [IN170.315(d)(2)(v)]

N/A

I hereby attest that all above statements are true, as an authorized signing authority on behalf of my organization.

Carolyn Doucette
9/15/16

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Appendix D: Auditing Actions (d.7) Attestation Template

Privacy and Security Certification Documentation

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Urgichart Version 1.0

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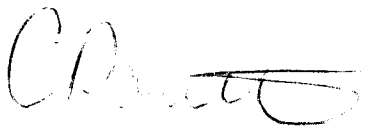
Test requirement:
Health IT developer submits documentation attesting no electronic health information is locally stored on the end-user device.

Foreruns System is a web based system that does not store electronic health information on end-user device.



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Accessibility-Centered Design (g.5) Attestation

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Forerun Systems does not use any health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of capabilities of each module in

170.315.a.1 Computerized Provider Order Entry (CPOE) - Medications
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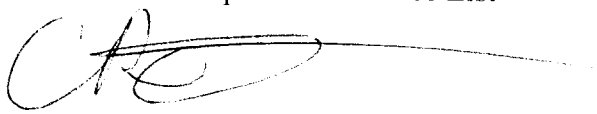

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