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Electronic Healthcare Management

Pulse Complete EHR 6.0 Usability Testing

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About This Document

This documentation describes the user-centered design processes that were applied to the twelve 2015 Edition Certification criteria to be included in the Safety-enhanced design - 45 CFR 170.315(g)(3) for which Pulse is seeking certification.

Report based on ISO/IEC 25062:2006 Common Industry Format for Usability Test Reports. NISTIR 7741 guidelines and NISTIR 7742 formatting were also used in the creation of this document.

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Contents

Usability Testing: Pulse Complete EHR 6.0 4

Executive Summary 4
Introduction 5
Method 6
Participants 6
Study Design 6
Tasks 7
Procedure 9
Test Location 10
Test Environment 10
Test Forms and Tools 10
Participant Instructions 10
Usability Metrics 11
Data Scoring 12
Results 13
Data Analysis and Reporting 13
Discussion of the Findings 14
Appendix A: Participant Demographics 23
Appendix B: Non-Disclosure Agreement 24
Appendix C: Informed Consent 25
Appendix D: EHRUT Usability Test (Moderator's Guide) 26
Task 1: Preliminary Questions/User Profile (10 minutes) 27
Task 2: Patient Demographics (5 minutes) 28
Task 3: Allergy List 29
Task 4: Medication List 30
Task 5: Problem List 31
Task 6: Implantable Device List 32
Task 7: Clinical Information Reconciliation 33
Task 8: CPOE - Laboratory 34
Task 9: CPOE – Diagnostic Imaging 35
Task 10: CPOE – Medication 36
Task 11: e-Prescribing 37
Task 12: Drug Interaction Checking 38
Task 13: Clinical Decision Support 39
Appendix E: System Usability Scale Questionnaire 40

Usability Testing: Pulse Complete EHR 6.0

Executive Summary

A usability test of PulseEHR Version 6.0 was conducted in the Pulse Office. The purpose of this test was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT). During the usability test, ten participants matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

This study collected data associated to twelve tasks typically performed within a clinical setting utilizing an EHR.

1. § 170.315 (a)(5) Demographics
2. § 170.315 (a)(8) Medication allergy list
3. § 170.315 (a)(7) Medication list
4. § 170.315 (a)(6) Problem list
5. § 170.315 (a)(14) Implantable device list
6. § 170.315 (b)(2) Clinical information reconciliation and incorporation
7. § 170.315 (a)(2) Computerized provider order entry – laboratory
8. § 170.315 (a)(3) Computerized provider order entry – diagnostic imaging
9. § 170.315 (a)(1) Computerized provider order entry – medications
10. § 170.315 (b)(3) Electronic prescribing
11. § 170.315 (a)(4) Drug-drug, drug-allergy interaction checks
12. § 170.315 (a)(9) Clinical decision support

During the 60 minute, one-on-one usability test, each participant was greeted by the testing moderator and asked to review and sign an Informed Consent and a Non-Disclosure Agreement. Participants with experience working with EHR systems were involved in the testing of all modules. Each participant had varying levels of the amount of past experience using EHR systems ranging from 1-10+ years. The tests were administered at the Pulse Systems offices and were monitored by the Director of Product Management and VP Clinical Quality & Regulatory Compliance.

Each user was tested individually, and seated at an MS-Windows-based machine. The participants were asked to follow simple instructions and achieve a specific result. Their workflow was monitored as to their ability to accomplish the task accurately and completely. The monitor also paid close attention to how easily they were able to determine the necessary workflow.

After the participants completed the tasks, they were given a short questionnaire to gather their thoughts on how efficient the workflow seemed to be and their general satisfaction level with the product. The participants were identified by an anonymous ID so that the individual was not traceable to the results. The results of the questionnaire and the real-time monitoring were tabulated and evaluated by members of the Product department for information about how well our design was accomplishing the goals of the participants.

The following types of data were collected for each participant:

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

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire and were compensated with small branded items – pens, t-shirts, USB drives, etc.

Various recommended metrics, in accordance with the 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 EHRUT. Following is a summary of the performance and rating data collected on the EHRUT.

Ease of Use

The overall ease of use mean was 3.1
The overall percent ease of use was 62%

Satisfaction

The overall subjective satisfaction mean was 3.2
The overall percent satisfaction was 64%

Introduction

The EHRUT tested for this study was Pulse Complete EHR version 6.0. Designed to present medical information to healthcare providers in private practice and ambulatory facilities, the EHRUT consists of an electronic medical records system with modules designed to allow the provider to capture, store and review patient medical findings. 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 EHRUT. To this end, measures of effectiveness, efficiency and user satisfaction, such as time to complete the tasks and ease of use, were captured during the usability testing.

Method

Participants

A total of 10 participants were tested on the EHRUT. Recruited participants had a mix of backgrounds and demographic characteristics. The following is a table of participants by characteristics, including demographics, occupation, education 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. In addition, participants had no direct connection to the development organization producing PulseEHR.

For the test purposes, end user characteristics were identified and potential participants were solicited.

User ID#	Sex	Age	Occupation/Role	Professional Experience (# months)	Computer Experience (Beginner, Intermediate, Advanced)	Product Experience (# months using PulseEHR)	Assistive Technology Needs (Vision, etc)
01	M	52	Physician	264	Advanced	84	N/A
02	M	44	Director HIT	300	Intermediate	120	N/A
03	F	32	IT Support	36	Advanced	36	N/A
04	M	32	Account Manager	24	Beginner	12	N/A
05	F	30	Analyst	18	Intermediate	18	N/A
06	F	40	Content Specialist	144	Intermediate	72	N/A
07	F	50	Marketing	300	Advanced	144	N/A
08	M	45	Designer	12	Beginner	12	N/A
09	F	26	IT Manager	36	Beginner	10	N/A
10	M	34	Administrator	72	Intermediate	72	N/A

Twelve participants (matching the criteria) were recruited and ten participated in the usability test. Two participants failed to show for the study due to unscheduled events.

Participants were scheduled for 90 minute sessions with 15 minutes in between each session for debrief by the administrator(s) and data logger(s), and to reset systems to proper test conditions. A spreadsheet was used to keep track of the participant schedule.

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.

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. 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.

Tasks

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

1. Preliminary Questions/User Profile
2. § 170.315 (a)(5) Demographics
    a. Locate and enter the patients sexual orientation as "Straight or Heterosexual"
    b. Locate and enter the patients Gender Identity as "Identifies as Male"
    c. Locate and enter the patients race as "Black or African American" with a more granular race code as "Haitian"
    d. Locate and enter the patients Ethnicity as "Not Hispanic or Latino"
    e. Locate and enter the patients preferred language as "French"
3. § 170.315 (a)(8) Medication allergy list
    a. Locate the penicillin allergy and edit the reaction to replace "Hives" with "Shortness of Breath".
    b. Enter the new allergy "peanut" into the patient's allergies but do not click save.
    c. Enter the Allergy Category of "Food" to the Peanut allergy.
    d. Enter the Reaction Type of "true allergy" to the Peanut allergy
    e. Enter reaction of "hives" to peanut and click save.
4. § 170.315 (a)(7) Medication list
    a. Locate the medication list and discontinue "Ceclor" with a reason of "Completed Rx"
    b. Search for drug Lisinopril 10mg tablet.
    c. Begin adding the drug Lisinopril 10mg tablet by bringing it in to the RX writer.
    d. Enter 'Once Daily" into the patient directions field.
    e. Click "Outside Provider" for the Physician.
    f. Save medication as "Currently Taking".
    g. Indicate that you have reviewed and reconciled the patient medication list with the patient by selecting the "reviewed/reconciled" action.
5. § 170.315 (a)(6) Problem list
    a. Locate the problem list and select Urinary Tract Infection, update the problem to reflect "resolved"
    b. Enter the new problem of essential hypertension.
6. § 170.315 (a)(14) Implantable device list
    a. Enter the UDI ((01)10884521062856(11)141231(17)150707(10)A213B1(21)1234) for patient device
    b. Review the following data elements to ensure data was retrieved:

i. GMDN PT name;
ii. Lot number;
iii. Expiration date;
iv. Mfg date; and
v. Serial number

c. Access the device entered above and mark it as removed.
d. Filter the list to show inactive devices.

7. § 170.315 (b)(2) Clinical information reconciliation and incorporation
   a. Import the CCD file from location (E:)
   b. Reconcile the patient medications
   c. Reconcile the patient allergies
   d. Reconcile the patient problem list
8. § 170.315 (a)(2) Computerized provider order entry – laboratory
   a. Add New test for Rapid Strep Test
   b. Select an Ordering Physician if this does not default
   c. Enter a Destination of "In House"
   d. Click Save

   NOTE: Since the testing environment is not hooked up to a true lab, administrator will result the test to simulate the result coming back from the interface.

   e. Review the resulted Strep Test
9. § 170.315 (a)(3) Computerized provider order entry – diagnostic imaging
   a. Add New test for Chest X-ray 2 views
   b. Select an Ordering Physician if this does not default
   c. Enter a Destination of "In House"
   d. Click Save

      NOTE: Since the testing environment is not hooked up to a true lab, administrator will result the test to simulate the result coming back from the interface.

   e. Review the resulted Chest X-ray
   f. Review the note attached to the result
10. § 170.315 (a)(1) Computerized provider order entry – medications
    a. Search for drug name Amoxicillin
    b. Begin prescribing Amoxicillin 500mg tablet
    c. Enter the patient directions "Take 2 tablets daily for 10 days."
    d. Edit the frequency to "3"
    e. Enter the Dispense # as "15"
    f. Enter the Packaging Qualifier as " Tablets
    g. Modify the refill quantity to include 2 refills
11. § 170.315 (b)(3) Electronic prescribing
    a. Search for drug name Amoxicillin

b. Begin prescribing Amoxicillin 500mg tablet
c. Enter the patient directions "Take 2 tablets daily for 10 days."
d. Enter the Dispense # as "15"
e. Enter the Packaging Qualifier as "Tablets"
f. Select Sally Jones as prescribing physician
g. Electronically transmit the prescription to "Testooo Pharmacy"

12. § 170.315 (a)(4) Drug-drug, drug-allergy interaction checks
    a. Perform an on-demand interaction checking for Pierre.
    b. Access the admin settings for Rx and change the settings to only show Absolute Contraindications for Pregnancy Precaution.
13. § 170.315 (a)(9) Clinical decision support
    a. Perform an on-demand interaction checking for Pierre. =
    b. Access the admin settings for Rx and change the settings to only show Absolute Contraindications for Pregnancy Precaution.
    c. Access the Clinical Information reconciliation that was performed earlier and run an on-demand clinical decision support analysis.
    d. Access health maintenance
    e. Edit the settings for the warfarin measure to "Auto Run".
    f. Edit the parameters to include is "Age in Range" to 18-65 years.

Tasks were selected based on their frequency of use and criticality of function. Also, tasks were based on those in which participants encounter a higher risk of data entry errors.

Procedure

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.

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.

Participants were instructed to perform the tasks:

- As quickly as possible making as few errors and deviations as possible.
- Without assistance; administrator was allowed to give immaterial guidance and clarification on tasks, but not instructions on use.

For each task, the participants were given a written copy of the task. Task timing began once the administrator finished reading the question and said "Begin now" The task time was stopped once the participant indicated they had successfully completed the task by saying "done". Participants were given 5 minutes to complete each task.

Following the session, the administrator gave the participant the post-test questionnaire (Appendix E) and thanked each individual for their participation.

Test Location

The test facility included a waiting area and a quiet testing room with a table, computer for the participants. Only the participants and administrator were in the test room. To ensure that the environment was comfortable for participants, noise levels were kept to a minimum with the ambient temperature within a normal range. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

Test Environment

The EHRUT would be typically be used in a healthcare office or facility. In this instance, the testing was conducted in the Pulse offices. For testing, the computer used a desktop computer, running Windows 10. The participants used a mouse and keyboard when interacting with the EHRUT. The application itself was running on a Windows-based machine using a test database on a WAN connection.

Technically, the system performance (i.e., response time) was representative to what actual participants would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

Test Forms and Tools

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

1. Moderator's Guide
2. Informed Consent
3. Non-Disclosure Agreement
4. Demographic Data Questionnaire
5. Post – Test Questionnaire

Examples of these documents can be found in Appendices (D, C, B, A, E) respectively. The Moderators guide was devised so as to be able to capture required data.

Participant Instructions

The administrator reads the following instructions aloud to each participant:

Thank for you participating in this study. Your input is very important. Our session today will last about 90 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. All of 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 10 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 the next task. Tasks are listed in the moderator's guide in Appendix D

Usability Metrics

The goal of testing is to determine the effectiveness, efficiency and satisfaction of the participants in the test. 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.

Efficiency of PulseEHR was measured by the amount of time it took participants to complete the tasks and any path deviations.

Effectiveness of PulseEHR was measured by the ability of the participants to complete the tasks accurately and completely.

Satisfaction was measured by a questionnaire given to the participants following each test about the ease of use.

An informal discussion between the participants and the moderator after the testing was completed provided comments and added to the measures of effectiveness and user satisfaction with the module. The metrics combined with the general comments were used to assist in the design process.

Data Scoring

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

	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 for each task. Task success was determined by assigning numeric weights for various levels of task success, as follows: Complete success (without assistance) = 1.0 Partial success = 0.5 Gives up or wrong answer = 0.0 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 1.5, allowing for some buffer because participants were not trained to expert performance and the user interface had been recently redesigned. When a task had multiple valid paths to successful outcome, each task path was timed and the average was multiplied by the buffer to obtain the target task time.
Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer, or performed it incorrectly, 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. A qualitative account of the observed errors and error types was collected.

Efficiency: Task Deviations	The participant's navigation path 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. 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 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.
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 task group and a post-session questionnaire. After each task group, the participant was asked to rate "Overall, these tasks were:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants.

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 correct, yield material, positive impact on user performance.

Discussion of the Findings

Task 2	§ 170.315 (a)(5) Demographics
Tasks: Task Success	Participants were asked to locate and enter the patient's Sexual Orientation and Gender Identity, Race, Ethnicity, and Preferred Language.
Effectiveness: Task Failures	All participants were able to complete the tasks within the time allotted. Participants with little experience took somewhat longer, but were able to finish within the expected time.
Efficiency: Task Deviations	Based on the questionnaire, participants were able to complete the tasks assigned. However, many struggled in locating where to enter the Gender Identity and Sexual Orientation.
Major Findings:	Users consistently demonstrated difficulty locating the area to document gender identity and sexual orientation. Inconsistent action functions caused users confusion between race, ethnicity and preferred language documentation.
Areas for Improvement:	Provide tool tips for location of demographic data entry areas such as gender identity and sexual orientation Design consistent input functionality when designating a single and multi-input function within a localized area of the application
Task 3	§ 170.315 (a)(8) Medication allergy list
Tasks: Task Success	Participants were asked to locate and edit an existing allergy, add a new food allergy, set the reaction type, and document that patient's reaction.

Effectiveness: Task Failures	Most participants were able to complete the tasks within the time allotted. Participants with little to no experience in the product we able to locate the component but were not able to complete the tasks.
Efficiency: Task Deviations	Based on the questionnaire, which asked the participants about their ability to understand the allergy list and make the specified changes, most participants reported being relatively satisfied with the workflow and their success in completing the tasks. There were participants that found the functionality cumbersome.
Major Findings:	Users demonstrated difficulty in adding and editing new allergies.
Areas for Improvement:	Focus on intuitive functions that allow users to follow consistent workflows when adding or editing throughout each module.
Task 4	§ 170.315 (a)(7) Medication list
Tasks: Task Success	Participants were asked to locate and take actions in the Medication list and take these actions: discontinue a medication and document the reason for discontinue, enter a new medication, document that medication directions, documenting the provider, and review/reconcile the patient medication list.
Effectiveness: Task Failures	All participants were able to complete the tasks within the time allotted. Participants with little experience took somewhat longer, but were able to finish within the expected time.

Efficiency: Task Deviations	Based on the questionnaire, participants were able to complete the tasks assigned. However, many struggled with the workflow for medication order entry. For some of the participants this was due to a lack of knowledge of the clinical workflows required for medication order entry.
Major Findings:	Users demonstrated difficulty in adding and editing new medications.
Areas for Improvement:	Focus on intuitive functions that allow users to follow consistent workflows when adding or editing throughout each module. Provide tool tips on hover action
Task 5	§ 170.315 (a)(6) Problem list
Tasks: Task Success	Participants were asked to locate and take these actions in the Problem List: edit and existing documented problem and enter a new problem into the system.
Effectiveness: Task Failures	All participants were able to complete the tasks within the time allotted. Participants with little experience took somewhat longer, but were able to finish within the expected time.
Efficiency: Task Deviations	Based on the questionnaire, participants were able to complete the tasks assigned.
Major Findings:	User demonstrated difficulty in editing problems already on the problem list.

Areas for Improvement:	Incorporate consistent edit actions across the application.
Task 6	§ 170.315 (a)(14) Implantable device list
Tasks: Task Success	Participates were asked to locate and add an implantable device to a patient's chart.
Effectiveness: Task Failures	All participants were able to complete the tasks within the time allotted. Participants with little experience took somewhat longer, but were able to finish within the expected time.
Efficiency: Task Deviations	Based on the questionnaire, participants were able to complete the tasks assigned.
Major Findings:	Users demonstrated successful documentation of implantable devices.
Areas for Improvement:	No recognizable areas of improvement at this time.
Task 7	§ 170.315 (b)(2) Clinical information reconciliation and incorporation
Tasks: Task Success	Participants were asked to import a existing CCD and reconcile the medications, allergies, and problems.

Effectiveness: Task Failures	Most participants were able to complete the tasks as assigned. Those participants that were not familiar with the software were not able to complete the CCD import, therefore, were not able to complete this task.
Efficiency: Task Deviations	The participants that were able to complete these tasks, were able to do so with little difficulty.
Major Findings:	User demonstrated difficulty locating the path to import the CCD for reconciliation. User demonstrated difficulty locating the completion of the reconciliation.
Areas for Improvement:	Provide prompts to complete reconciliation actions Embed CCD paths to reduce browsing needs
Task 8	§ 170.315 (a)(2) Computerized provider order entry – laboratory
Tasks: Task Success	Participants were asked to location the Lab Order module, add a test, select an Ordering Physician, and select a destination for a new lab order.
Effectiveness: Task Failures	Participants completed all of the tasks as described by the questionnaire. However, participants had difficulty locating the Lab Order module. This was due to unfamiliarity with the application.
Efficiency: Task Deviations	The participants that were able to complete these tasks, were able to do so with some difficulty.
Major Findings:	Users experienced frustration with the amount of clicks needed to create an order for lab tests. Users were consistently restricted from saving an order due to not having an ordering provider selected.
Areas for Improvement:	Look at efficiency in workflow to reduce the number of steps taken. Look at ways to identify and prepopulate fields based on patients appointment provider or assigned provider. Look at areas where we can create quick lists (list of favorite orders).

Task 9	§ 170.315 (a)(3) Computerized provider order entry – diagnostic imaging
Tasks: Task Success	Participants were asked to locate the Lab Orders module, add a new test for a Chest X-Ray, select an ordering physician, and set the destination as In-House.
Effectiveness: Task Failures	All participants were able to complete the tasks within the time allotted. Participants with little experience took somewhat longer, but were able to finish within the expected time.
Efficiency: Task Deviations	The participants that were able to complete these tasks, were able to do so with little difficulty.
Major Findings:	Users experienced frustration with the amount of clicks needed to create an order for lab tests Users were consistently restricted from saving an order due to not having an ordering provider selected Module does not allow for smart search or abbreviation on common medical terms
Areas for Improvement:	Look at efficiency in workflow to reduce the number of steps taken Look at ways to identify and prepopulate fields based on patients appointment provider or assigned provider Look at areas where we can create quick lists (list of favorite orders) Incorporation of smart search functionality to replace exact match functionality
Task 10	§ 170.315 (a)(1) Computerized provider order entry – medications
Tasks: Task Success	Participants were asked to locate the Rx Module, search for a medication, prescribe Amoxicillin 500 mg, and complete the SIG information for the prescription. Additionally, they were asked to edit an existing prescription.
Effectiveness: Task Failures	All participants were able to complete the tasks within the time allotted. Participants with little experience took somewhat longer, but were able to finish within the expected time.

Efficiency: Task Deviations	Based on the questionnaire, the participants were able to complete the tasks as assigned.
Major Findings:	Users found it difficult to identify missing fields that were preventing the action from being completed (pharmacy, prescriber, quantity).
Areas for Improvement:	Instead of populating message identifying missing data at the top of the screen look at indicators to call out the field with the screen.
Task 11	§ 170.315 (b)(3) Electronic prescribing
Tasks: Task Success	Participants were asked to access the Rx Module, prescribe a new medication, add patient directions, and dispense information, packaging, prescriber, and pharmacy information.
Effectiveness: Task Failures	All participants were able to complete the tasks within the time allotted. Participants with little experience took somewhat longer, but were able to finish within the expected time.
Efficiency: Task Deviations	The participants that were able to complete these tasks, were able to do so with no difficulty.
Major Findings:	Users consistently demonstrate confusion of completing eRx action due to not having a valid pharmacy selected.

Areas for Improvement:	Provide workflow reminders on screen to users of how to complete the actions based on missing data elements.
Task 12	§ 170.315 (a)(4) Drug-drug, drug-allergy interaction checks
Tasks: Task Success	Participants were asked to accessed the Rx Module and add a new medication that would trigger a drug interaction for the patient.
Effectiveness: Task Failures	All participants were able to complete the tasks within the time allotted. Participants with little experience took somewhat longer, but were able to finish within the expected time.
Efficiency: Task Deviations	The participants that were able to complete these tasks, were able to do so with no difficulty.
Major Findings:	Users demonstrated inability to locate setting menu to adjust integration settings based on practice needs. Users were not always able to locate the on demand button to trigger the interaction.
Areas for Improvement:	Could look at ways to incorporate menu from RX module directly as opposed to making users exit the RX Module and accessing another module to change preferences/settings. Look at more intuitive icons that represent the action needed.
Task 13	§ 170.315 (a)(9) Clinical decision support
Tasks: Task Success	Participants were asked to access the Rx Module, perform on-demand interaction checking, and make changes to the settings for Clinical Decision support.

Effectiveness: Task Failures	All participants were able to complete the tasks within the time allotted. Participants with little experience took somewhat longer, but were able to finish within the expected time.
Efficiency: Task Deviations	The participants that were able to complete these tasks, were able to do so with no difficulty.
Major Findings:	Almost all users demonstrated the inconsistency of modules by double clicking to bring the item in to edit mode as discovered the double click function does not apply to this module. Users were not aware of how to attach reference materials to clinical decision support.
Areas for Improvement:	Improve documentation in release notes and end user guides that relate to workflows Look at ways to offer inline help to areas within the application to guide user experience

Appendix A: Participant Demographics

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

Gender

☐ Male

☐ Female

Age

☐ 18-24 years

☐ 25-34 years

☐ 35-44 years

☐ 45-54 years

☐ 55+

Education

☐ High School

☐ Associates Degree

☐ Bachelor's Degree

☐ Master's Degree

☐ Doctorate Degree

Occupation/Role

☐ RN/BSN

☐ Physician

☐ Admin

☐ Information Technology

☐ Front Desk/Scheduling

☐ Medical Assistant

☐ Other: (Specify)_____

Computer Experience

☐ None

☐ 1-3 years

☐ 4-7 years

☐ 8-11 years

☐ 11 years +

Appendix B: Non-Disclosure Agreement

Non-Disclosure Agreement

This agreement is entered into as of _____, 2017, between _____ ("the Participant") and the testing organization Pulse Systems Inc., located at 3020 Cypress Drive, Wichita, Kansas, 67226.

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

By way of illustration, but not limitation, Confidential Information includes trade secrets, processes, formulae, date, know-how, products, designs, drawings, computer aided design files and other computer files, computer software, ideas, improvements, inventions, training methods and materials, marketing techniques, plans, strategies, budgets, financial information, or forecasts.

Any information the Participant acquires relating to this product during this study is confidential and proprietary to Pulse Systems and is being disclosed solely for the purposes of the Participant's participation in today's usability study. By signing this form the Participant acknowledges that he/she will receive compensation for feedback and will not disclose this confidential information obtained today to anyone else or any other organizations.

Participant's printed name: _____

Signature: _____Date:_____

Appendix C: Informed Consent

Pulse Systems would like to thank you for participating in this study. The purpose of this study is to evaluate tasks typically completed within an electronic health records system. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about 60 minutes. At the conclusion of the test, you will be compensated for your time.

Agreement

I understand and agree that as a voluntary participant in the present study conducted by Pulse Systems I am free to withdraw consent or discontinue participation at any time. I understand and agree to participate in the study conducted and recorded by Pulse Systems.

I understand and consent to the use of the recording by Pulse Systems. I understand that the information will be used for research purposes only and that my name and image will not be used for any purpose other than research. I relinquish any rights to the information received during this study by Pulse Systems.

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

I understand and agree that data confidentiality is assured, because only de-identified data – i.e., identification numbers not names - will be used in analysis and reporting of the results.

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

Please check one of the following:

☐ YES, I have read the above statement and agree to participate.

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

Participant's printed name: _____

Signature: _____Date:_____

Appendix D: EHRUT Usability Test (Moderator's Guide)

Administrator: _____ Date: _____

Data Logger: _____ Time: _____

Participant #:_____ Location:_____

Prior to testing:

- Confirm schedule with participant
- 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

Orientation (15 minutes)

Thank you for agreeing to participate in this usability study. Our session today will last 60 minutes. During that time you will take a look at an electronic health record system in order to assist us in evaluating workflows pertaining to clinical features within our Pulse application.

Shortly, I will ask you to complete a few tasks using this system and answer some questions. We are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. You will be asked to complete these tasks on your own trying to do them as quickly as possible with the fewest possible errors or deviations. Do not do anything more than asked. If you get lost or have difficulty I cannot help you with anything to do with the system itself. Please save your detailed comments until the end of the session. The data logger and myself will be taking notes.

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

The product you will be using today is an early prototype of PulseEHR version 6.0. Some of the data may not be clinically accurate, and we understand that it may not be applicable to your specialty.

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

Do you have any questions or concerns?

Gather signed Non-Disclosure Agreement and Informed Consent Form.

Task 1: Preliminary Questions/User Profile (10 minutes)

1. Please tell me a little bit about yourself such as:
    a. Age
    b. What is your current job title and role at your organization?
    c. How long have you been working in this role?
    d. What are some of your main responsibilities?
2. Which features of the product do you use most frequently? Please list your top 2 or 3.
3. What are your top 2 main likes/dislikes about PulseEHR?
4. On a scale of 1-5 with 5 being the most familiar, how would you rate your level of expertise on the following features within Pulse?

a.	Adding/Reviewing Allergies	1	2	3	4	5
b.	Adding/Reviewing Medications	1	2	3	4	5
c.	Reviewing Drug Interactions	1	2	3	4	5
d.	Prescribing a Medication (eRx)	1	2	3	4	5
e.	Adding Implantable Devices	1	2	3	4	5
f.	Creating/Modifying Orders	1	2	3	4	5
	i. Labs	1	2	3	4	5
	ii. Medications	1	2	3	4	5
	iii. Referrals	1	2	3	4	5
g.	Creating/Receiving CCDs	1	2	3	4	5
h.	Adding/Modifying Demographics	1	2	3	4	5
i.	Reviewing Patient Alerts (CDS)	1	2	3	4	5
j.	Adding/Reviewing Patient Problems	1	2	3	4	5
k.	Reconciling Clinical Information1	1	2	3	4	5

5. Tell me about your experience with electronic health records.

Task 2: Patient Demographics (5 minutes)

For this task, you will be looking at PulseEHR patient demographics, populated with fake patient information. I will be asking you to perform tasks associated to patient demographics. I will ask you to start when I say "BEGIN NOW" and please indicate you are finished by saying "DONE".

Scenario 1: Patient **Pierre Cosway** has come in to the office today as a New Patient with cough and sore throat. He has brought in his new patient forms that were mailed to him. He has stated on his form the following demographics:

- Race: Black or African American (CDC: 2054-5), Haitian (CDC: 2071-9)
- Ethnicity: Not Hispanic or Latino (CDC: 2186-5)
- Preferred Language: French (ISO: fr)
- Sexual Orientation: Straight or heterosexual (SNOMED: 20430005)
- Gender Identity: Identifies as Male (SNOMED: 446151000124109)

Begin Tasks:

1. Open the patient demographics screen for Pierre Cosway
2. Locate and enter the patients sexual orientation as "Straight or Heterosexual" **Begin Now** (record start/stop time)
3. Locate and enter the patients Gender Identity as "Identifies as Male" **Begin Now** (record start/stop time)
4. Locate and enter the patients race as "Black or African American" with a more granular race code as "Haitian" **Begin Now** (record start/stop time)
5. Locate and enter the patients Ethnicity as "Not Hispanic or Latino" **Begin Now** (record start/stop time)
6. Locate and enter the patients preferred language as "French" **Begin Now** (record start/stop time)

Total Task Time: _____Minutes

Success:

☐ Not Completed
☐ Easily Completed
☐ Completed with difficulty; Describe:

Rating:

On a scale of 1-5, where 1 = very difficult and 5 = very easy to use, overall, how would you rate the ease of use of the tasks in this feature set?

1 2 3 4 5

Observed Errors and Verbal Comments:

Facilitator Comments:

Task 3: Allergy List

Now that we have the patient entered correctly into our system, our next task will be around patient allergies.

Scenario 1: You are reviewing/reconciling the patient allergies with the patient and **Pierre Cosway** indicates that his reactions to penicillin are not correct. He experiences shortness of breath NOT hives when he takes penicillin. He also indicates that he has developed a new allergy to Peanut with a reaction of hives.

Begin Tasks:

1. Open the patient chart for **Pierre Cosway** and access the Allergy List through the RX Module.
2. Locate the allergy panel and select penicillin and edit the reaction to replace "Hives" with "Shortness of Breath". **Begin Now** (record start/stop time)
3. Enter the new allergy "peanut" into the patient's allergies but do not click save. **Begin Now** (record start/stop time)
4. Enter the Allergy Category of "Food" to the Peanut allergy. **Begin Now** (record start/stop time)
5. Enter the Reaction Type of "true allergy" to the Peanut allergy. **Begin Now** (record start/stop time)
6. Enter reaction of "hives" to peanut and click save. **Begin Now** (record start/stop time)

Total Task Time: _____Minutes

Success:

☐ Not Completed
☐ Easily Completed
☐ Completed with difficulty; Describe:

Rating:

On a scale of 1-5, where 1 = very difficult and 5 = very easy to use, overall, how would you rate the ease of use of the tasks in this feature set?

1 2 3 4 5

Observed Errors and Verbal Comments:

Facilitator Comments:

Task 4: Medication List

Now that we have the patient entered correctly into our system and allergies have been reviewed, we will move on to review/reconcile the patient medication list.

Scenario: while reviewing the medication list, you notice that he had previously taken Ceclor for a previous infection which was not discontinued after use. Patient indicated that he indeed completed the medication so it is safe to discontinue. He also states that he has been prescribed Lisinopril once daily for high blood pressure.

Begin Tasks:

1. Open the patient chart for **Pierre Cosway** and access the medication list.
2. Locate the medication list and discontinue "Ceclor" with a reason of "Completed Rx" **Begin Now** (record start/stop time)
3. Search for drug Lisinopril 10mg tablet. **Begin Now** (record start/stop time)
4. Begin adding the drug Lisinopril 10mg tablet by bringing it in to the RX writer. **Begin Now** (record start/stop time)
5. Enter "Once Daily" into the patient directions field. **Begin Now** (record start/stop time)
6. Click "Outside Provider" for the Physician. **Begin Now** (record start/stop time)
7. Save medication as "Currently Taking". **Begin Now** (record start/stop time)
8. Indicate that you have reviewed and reconciled the patient medication list with the patient by selecting the "reviewed/reconciled" action. **Begin Now** (record start/stop time)

Total Task Time: _____Minutes

Success:

☐ Not Completed
☐ Easily Completed
☐ Completed with difficulty; Describe:

Rating:

On a scale of 1-5, where 1 = very difficult and 5 = very easy to use, overall, how would you rate the ease of use of the tasks in this feature set?

1 2 3 4 5

Observed Errors and Verbal Comments:

Facilitator Comments:

Task 5: Problem List

Scenario: Proceeding on with rooming the patient, we need to review the patients problem list. Patient indicates he no longer has the UTI but does have hypertension.

Begin Tasks:

1. Open the patient chart for **Pierre Cosway** and access the problem list.
2. Locate Urinary Tract Infection, update the problem to reflect "resolved" **Begin Now** (record start/stop time)
3. Enter the new problem of essential hypertension. **Begin Now** (record start/stop time)

Total Task Time: _____Minutes

Success:

☐ Not Completed
☐ Easily Completed
☐ Completed with difficulty; Describe:

Rating:

On a scale of 1-5, where 1 = very difficult and 5 = very easy to use, overall, how would you rate the ease of use of the tasks in this feature set?

1 2 3 4 5

Observed Errors and Verbal Comments:

Facilitator Comments:

Task 6: Implantable Device List

Scenario: Upon review with the patient, Pierre indicated that he has an inserted device to prevent any future cardiac arrhythmias.

Begin Tasks:

1. Open the patient chart for **Pierre Cosway** and access the Implantable Device List.
2. Enter the UDI ((01)10884521062856(11)141231(17)150707(10)A213B1(21)1234) for patient device **Begin Now** (record start/stop time)
3. Select the arrow to the right of the UDI Number.
4. Select the icon to add the device to the patients chart. **Begin Now** (record start/stop time)
5. Review the following data elements to ensure data was retrieved **Begin Now** (record start/stop time):
    a. GMDN PT name;
    b. Lot number;
    c. Expiration date;
    d. Mfg date; and
    e. Serial No.
3. Access the device entered above and mark it as removed. **Begin Now** (record start/stop time)
4. Filter the list to show inactive devices. **Begin Now** (record start/stop time)

Total Task Time: _____Minutes

Success:

☐ Not Completed
☐ Easily Completed
☐ Completed with difficulty; Describe:

Rating:

On a scale of 1-5, where 1 = very difficult and 5 = very easy to use, overall, how would you rate the ease of use of the tasks in this feature set?

1 2 3 4 5

Observed Errors and Verbal Comments:

Facilitator Comments:

Task 7: Clinical Information Reconciliation

Scenario: Upon review with the patient, Pierre indicated that he has recently visited his cardiologist and that provider is also an EMR user. The care team was updated and the doctor had sent a secure message containing the CCD. Your front desk staff has attached the document to the patient. You need to reconcile the clinical information.

Begin Tasks:

1. Open the patient chart for **Pierre Cosway** and access the CCD Manager.
2. Import the CCD file from location (E:) **Begin Now** (record start/stop time)
3. Reconcile the patient medications **Begin Now** (record start/stop time)
4. Reconcile the patient allergies **Begin Now** (record start/stop time)
5. Reconcile the patient problem list **Begin Now** (record start/stop time)

Total Task Time: _____Minutes

Success:

☐ Not Completed
☐ Easily Completed
☐ Completed with difficulty; Describe:

Rating:

On a scale of 1-5, where 1 = very difficult and 5 = very easy to use, overall, how would you rate the ease of use of the tasks in this feature set?

1 2 3 4 5

Observed Errors and Verbal Comments:

Facilitator Comments:

Task 8: CPOE - Laboratory

Scenario: Based on the physical exam of white patches on the back area of throat, you indicate the need to order a rapid strep test.

Begin Tasks:

1. Open the patient chart for **Pierre Cosway** and access the Lab Orders module
2. Add New test for Rapid Strep Test **Begin Now** (record start/stop time)
3. Select an Ordering Physician if this does not default **Begin Now** (record start/stop time)
4. Enter a Destination of "In House" **Begin Now** (record start/stop time)
5. Click Save

NOTE: Since the testing environment is not hooked up to a true lab, administrator will result the test to simulate the result coming back from the interface. **Test result: POS**

6. Review the resulted Strep Test **Begin Now** (record start/stop time)

Total Task Time: _____Minutes

Success:

☐ Not Completed
☐ Easily Completed
☐ Completed with difficulty; Describe:

Rating:

On a scale of 1-5, where 1 = very difficult and 5 = very easy to use, overall, how would you rate the ease of use of the tasks in this feature set?

1 2 3 4 5

Observed Errors and Verbal Comments:

Facilitator Comments:

Task 9: CPOE – Diagnostic Imaging

Scenario: patient also presented with wheezing, you indicated the need to order a chest x-ray

Begin Tasks:

1. Open the patient chart for **Pierre Cosway** and access the Lab Orders Module
2. Add New test for Chest X-ray 2 views **Begin Now** (record start/stop time)
3. Select an Ordering Physician if this does not default **Begin Now** (record start/stop time)
4. Enter a Destination of "In House" **Begin Now** (record start/stop time)
5. Click Save

NOTE: Since the testing environment is not hooked up to a true lab, administrator will result the test to simulate the result coming back from the interface. **Test result: Normal, Note: No evidence of fluid in the lungs.**

6. Review the resulted Chest X-ray **Begin Now** (record start/stop time)
7. Review the note attached to the result **Begin Now** (record start/stop time)

Total Task Time: _____Minutes

Success:

☐ Not Completed
☐ Easily Completed
☐ Completed with difficulty; Describe:

Rating:

On a scale of 1-5, where 1 = very difficult and 5 = very easy to use, overall, how would you rate the ease of use of the tasks in this feature set?

1 2 3 4 5

Observed Errors and Verbal Comments:

Facilitator Comments:

Task 10: CPOE – Medication

Scenario: Based on the physical exam and results of the strep test, you indicate the need to prescribe amoxicillin for the patient as he now has strep throat.

Begin Tasks:

1. Open the patient chart for **Pierre Cosway** and access the Rx Module.
2. Search for drug name Amoxicillin **Begin Now** (record start/stop time)
3. Begin prescribing Amoxicillin 500mg tablet **Begin Now** (record start/stop time)
4. Enter the patient directions "Take 2 tablets daily for 10 days." **Begin Now** (record start/stop time)
5. Edit the frequency to "3" **Begin Now** (record start/stop time)
6. Enter the Dispense # as "15" **Begin Now** (record start/stop time)
7. Enter the Packaging Qualifier as " Tablets" **Begin Now** (record start/stop time)
8. Modify the refill quantity to include 2 refills **Begin Now** (record start/stop time)

Total Task Time: _____Minutes

Success:

☐ Not Completed
☐ Easily Completed
☐ Completed with difficulty; Describe:

Rating:

On a scale of 1-5, where 1 = very difficult and 5 = very easy to use, overall, how would you rate the ease of use of the tasks in this feature set?

1 2 3 4 5

Observed Errors and Verbal Comments:

Facilitator Comments:

Task 11: e-Prescribing

Scenario: Based on the physical exam and results of the strep test, you indicate the need to prescribe amoxicillin for the patient as he now has strep throat.

Begin Tasks:

1. Open the patient chart for **Pierre Cosway** and access the Rx Module.
2. Search for drug name Amoxicillin **Begin Now** (record start/stop time)
3. Begin prescribing Amoxicillin 500mg tablet **Begin Now** (record start/stop time)
4. Enter the patient directions "Take 2 tablets daily for 10 days." **Begin Now** (record start/stop time)
5. Enter the Dispense # as "15" **Begin Now** (record start/stop time)
6. Enter the Packaging Qualifier as "Tablets" **Begin Now** (record start/stop time)
7. Select Sally Jones as prescribing physician **Begin Now** (record start/stop time)
8. Electronically transmit the prescription to "Testooo Pharmacy" **Begin Now** (record start/stop time)

Total Task Time: _____Minutes

Success:

☐ Not Completed
☐ Easily Completed
☐ Completed with difficulty; Describe:

Rating:

On a scale of 1-5, where 1 = very difficult and 5 = very easy to use, overall, how would you rate the ease of use of the tasks in this feature set?

1 2 3 4 5

Observed Errors and Verbal Comments:

Facilitator Comments:

Task 12: Drug Interaction Checking

Scenario: Prescribing Amoxicillin triggers an interaction with the allergy to Penicillin.

Begin Tasks:

1. Open the patient chart for **Pierre Cosway** and access the Rx Module.
2. Perform an on-demand interaction checking for Pierre. **Begin Now** (record start/stop time)
3. Access the admin settings for Rx and change the settings to only show Absolute Contraindications for Pregnancy Precaution. **Begin Now** (record start/stop time)

Total Task Time: _____Minutes

Success:

☐ Not Completed
☐ Easily Completed
☐ Completed with difficulty; Describe:

Rating:

On a scale of 1-5, where 1 = very difficult and 5 = very easy to use, overall, how would you rate the ease of use of the tasks in this feature set?

1 2 3 4 5

Observed Errors and Verbal Comments:

Facilitator Comments:

Task 13: Clinical Decision Support

Scenario: Prescribing Amoxicillin triggers an interaction with the allergy to Penicillin

Begin Tasks:

1. Open the patient chart for **Pierre Cosway** and access the Rx Module.
2. Perform an on-demand interaction checking for Pierre. **Begin Now** (record start/stop time)
3. Access the admin settings for Rx and change the settings to only show Absolute Contraindications for Pregnancy Precaution. **Begin Now** (record start/stop time)
4. Access the Clinical Information reconciliation that was performed earlier and run an on-demand clinical decision support analysis. **Begin Now** (record start/stop time)
5. Access health maintenance
6. Edit the settings for the warfarin measure to "Auto Run". **Begin Now** (record start/stop time)
7. Edit the parameters to include is "Age in Range" to 18-65 years. **Begin Now** (record start/stop time)

Total Task Time: _____Minutes

Success:

☐ Not Completed
☐ Easily Completed
☐ Completed with difficulty; Describe:

Rating:

On a scale of 1-5, where 1 = very difficult and 5 = very easy to use, overall, how would you rate the ease of use of the tasks in this feature set?

1 2 3 4 5

Observed Errors and Verbal Comments:

Facilitator Comments:

Appendix E: System Usability Scale Questionnaire

Use the scale to answer the following questionnaire:

1 = Strongly disagree 5 = 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