

Agastha Enterprise Healthcare Software 15.1

**Customized Common Industry
Format Template for Electronic
Health Record Usability Testing**

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EHR Usability Test Report of Agastha Healthcare Enterprise Software Version 15.1

Report based on ISO/IEC25062:2006 Common Industry Format for Usability Test Reports

Agastha Enterprise Healthcare Software Version 15.1

Date of Usability Test: 12/11/2017
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1. EXECUTIVE SUMMARY

A usability test of Agastha Enterprise Healthcare Software, Version 15.1, an Ambulatory EHR was conducted on 12/11/2017 in North Miami Beach, Florida by American Elite Tech, Inc. 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, 10 healthcare providers [and/or other intended users] matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

This study collected performance data on 12 tasks typically conducted on an EHR:

1. Ordering medications
2. Ordering laboratory tests
3. Ordering diagnostic imaging tests
4. Avoiding drug-drug, drug-allergy, and food-allergy interactions
5. Creating and editing demographics data
6. Maintaining the problem list
7. Maintaining and reconciling the medication list
8. Maintaining the medication allergy list
9. Interpreting the recommendations from clinical decision support
10. Using the clinical information reconciliation and incorporation
11. Performing clinical information reconciliation and incorporation
12. Electronic prescribing of medications

During the 90 minutes one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form (included in Appendix 3); they were instructed that they could withdraw at any time. Some participants had prior experience with the EHR while some did not.

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 and,

along with the data logger recorded user performance data on paper and electronically. The administrator did not give the participant assistance in how to complete the task.

Participant screens, head shots and audio were not recorded.

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 \$50 for their time. 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

1. Data Summary

Table 1. Performance and rating data

Measure	N	Task Success	Path Deviation	Task Time		Errors	Task Ratings 5=Easy
				Mean (SD) Sec	Deviations (Observed/Optimal)		
Task	#	%	Deviations (Observed/Optimal)	Mean (SD) Sec	Deviations (Observed/Optimal)	%	Mean (SD)
1. Computerized provider order entry - Medications	10	70%	25/8	225	301/225	30%	4
2. Computerized provider order entry - Laboratory	10	100%	8/5	225	275/225	0%	5
3. Computerized provider order entry - Radiology	10	100%	7/5	225	290/225	0%	5
4. Drug-drug, drug-allergy interaction checks	10	100%	11/5	225	290/225	0%	5
5. Demographics	10	96%	44/30	325	484/325	4%	4
6. Problem List	10	100%	7/5	225	232/225	0%	5
7. Medication List	10	100%	11/5	225	227/225	0%	5
8. Medication allergy list	10	100%	8/5	225	233/225	0%	5
9. Clinical decision support	10	50%	52/35	375	538/375	50%	2.5
10. Implantable Device	10	75%	45/20	375	512/375	25%	4
11. Clinical information reconciliation	10	79.4%	143/100	525	613/525	20.6%	3.4
12. Electronic prescribing	10	93.3%	9/6	375	455/375	6.7%	4.3

2. INTRODUCTION

The EHRUT tested for this study was **Agastha Enterprise Healthcare Software, Version 15.1**. Designed to present medical information to healthcare providers in an ambulatory setting. The usability testing attempted to represent realistic exercises and conditions.

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

3. METHOD

3.1 PARTICIPANTS

A total of 10 participants were tested on the EHRUT. Participants in the test were doctors, clinicians and students. Participants were recruited by American Elite Tech, Inc. and were compensated \$50 for their time. In addition, participants had no direct connection to the development of or organization producing the EHRUT. Participants were not from the testing or supplier organization. Participants were given the opportunity to have the same orientation and level of training as the actual end users would have received.

For the test purposes, end-user characteristics were identified and translated into a recruitment screener used to solicit potential participants.

Recruited participants had a mix of backgrounds and demographic characteristics conforming to the recruitment screener. The following is a table of participants by characteristics, including demographics, professional experience, computing experience and user needs for assistive technology. Participant names were replaced with Participant IDs so that an individual’s data cannot be tied back to individual identities.

**Table 2.
Participants
Summary**

Participant Identifier	Gender	Age	Participant Education	Professional Experience	Occupation/Role	Computer Experience	Product Experience
ID01	Male	50-60	Bachelor's Degree	24	Medical Administrator	200	24
ID02	Female	20-30	No High School Degree	6	Student	48	1
ID03	Male	50-60	Doctorate Degree	60	Doctor	360	60
ID04	Female	40-50	Bachelor's Degree	204	Clinical Administrator	190	60

ID05	Male	50-60	High School Graduate	12	Front Office	80	12
ID06	Male	60-70	Doctorate degree	300	Doctor	240	60
ID07	Female	20-30	No High School Degree	8	Student	50	8
ID08	Female	20-30	No High School Degree	12	Administrator	74	12
ID09	Male	20-30	No High School Degree	1	Student	60	1
ID10	Female	20-30	No High School Degree	1	Student	70	1

10 participants (matching the demographics in the section on Participants) were recruited and 10 participated in the usability test. 0 participants failed to show for the study.

Participants were scheduled for 5 minutes sessions with 3 minutes in between each session for debrief by the administrator and data logger, and to reset systems to proper test conditions. A spreadsheet was used to keep track of the participant schedule, and included each participant’s demographic characteristics as provided by the recruiting firm.

3.2 STUDY DESIGN

Overall, the objective of this test was to uncover areas where the application performed well – that is, effectively, efficiently, and with satisfaction – and areas where the application failed to meet the needs of the participants. The data from this test may serve as a baseline for future tests with an updated version of the same EHR and/or comparison with other EHRs provided 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 1 EHR. Each participant used the system in the same location, and was provided with the same instructions. The system was evaluated for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

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

- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

3.3 TASKS

Tasks were designed based on the 2015 Edition Health IT Certification criteria and NISTIR 7741. They were also based on the criticality of function and frequency of use. As part of the design, Agastha used risk management principles to create testing procedures that would be realistic and representative of the kinds of activities a user might do with the EHR. Tasks were prioritized according to risk associated with user errors and were created based on design areas related to known user errors.

Following are the tasks that users were assigned:

CPOE Medications (315.a.1)

- ◆ Record Medication Order
- ◆ Change Medication Order
- ◆ Access Medication Order

CPOE Laboratory (315.a.2)

- Record Laboratory Order
- Change Laboratory Order
- Access Laboratory Order

CPOE Radiology (315.a.3)

- Record Radiology/imaging Order
- Change Radiology/imaging Order
- Access Radiology/imaging Order

Drug-drug, drug-allergy interactions checks (315.a.4)

- Create drug-drug and drug-allergy interventions prior to CPOE completion
- Adjustment of severity level of drug-drug interventions

Demographics(315.a.5)

- Enable a user to record, change, and access patient demographic data including race, ethnicity, preferred language, sex, sexual orientation, gender identity, and date of birth.

Problem list (315.a.6)

- Record Problem List
- Change Problem List
- Access Problem List

Medication list (315.a.7)

- Record Medication List
- Change Medication List
- Access Medication List

Medication allergy list (315.a.8)

- Record Medication Allergy List
- Change Medication Allergy List
- Access Medication Allergy List

Clinical decision support (315.a.9)

- Problem List Interventions
- Medication List Interventions
- Medication Allergy List Interventions
- Demographics Interventions
- Lab Tests and Results Interventions
- Vital Signs Interventions
- Identify User Diagnostic and Therapeutic Reference Information

Implantable Device (315.a.14)

- The user records the unique device identifiers for a patient's implantable device in all formats established by the 3 UDI Issuing Agencies.

Clinical information reconciliation (315.b.2)

- Reconcile patient's active medication list with another source
- Reconcile patient's active problem list with another source
- Reconcile patient's active medication allergy list with another source
- Review and validate reconciled list

Electronic prescribing (315.b.3)

- Create prescriptions
- Cancel prescriptions
- Refill prescriptions
- Receive fill status
- Request and receive medication history

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

4. PROCEDURES

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

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

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

Participants were instructed to perform the tasks:

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

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

Following the session, the administrator gave the participant the post-test questionnaire, compensated them for their time, and thanked each individual for their participation.

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

Participants were thanked for their time and compensated. Participants signed a receipt and acknowledgement form indicating that they had received the compensation.

4.1 TEST ENVIRONMENT

The EHRUT would typically be used in a healthcare office or facility.

In this instance, the testing was conducted in American Elite Tech, Inc. facilities. For testing, the computer used personal computers running Windows 10.

The participants used a mouse and keyboard when interacting with the EHRUT.

The EHRUT used resolutions of 1366 x 768 and 1280 x 768. The application was set up by American Elite Tech, Inc. according to the vendor's documentation describing the system set-up and preparation. The application itself was running on a Java based platform using an Oracle DB on a WAN connection. Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

4.2 TEST FORMS AND TOOLS

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

1. Informed Consent
2. Moderator's Guide
3. Post-test Questionnaire
4. Incentive Receipt and Acknowledgment Form

The participant's interaction with the EHRUT were not captured and recorded.

The test session were electronically transmitted to a nearby observation room where the data logger observed the test session.

4.3 PARTICIPANT INSTRUCTIONS

The administrator read the following instructions aloud to the each participant:

Thank you for 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. I did not have any involvement in its creation, so please be honest with your opinions. 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 time 5 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.

4.4 USABILITY METRICS

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

The goals of the test were to assess:

1. Effectiveness of [EHRUT] by measuring participant success rates and errors
2. Efficiency of [EHRUT] by measuring the average task time and path deviations

3. Satisfaction with [EHRUT] by measuring ease of use ratings

4.5 DATA SCORING

The following table (Table 3) details how tasks were scored, errors evaluated, and the time data analyzed.

Table 3. Details of how observed data were scored.

Measures	Rationale and Scoring
<p>Effectiveness: Task Success</p>	<p>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.</p> <p>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.</p> <p>Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency.</p> <p>Optimal task performance time, as benchmarked by expert performance under realistic conditions, is recorded when constructing tasks. Target task times used for task times in the Moderator’s Guide must be operationally defined by taking multiple measures of optimal performance and multiplying by some factor [e.g., 1.25] that allows some time buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was [x] seconds then allotted task time performance was [x * 1.25] seconds. This ratio should be aggregated across tasks and reported with mean and variance scores.</p>

<p>Effectiveness: Task Failures</p>	<p>If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as an “Failures.” No task times were taken for errors.</p> <p>The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors. This should also be expressed as the mean number of failed tasks per participant.</p> <p>On a qualitative level, an enumeration of errors and error types should be collected.</p>
<p>Efficiency: Task Deviations</p>	<p>The participant’s path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation.</p> <p>It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.</p>

<p>Efficiency: TaskTime</p>	<p>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.</p>
<p>Satisfaction: Task Rating</p>	<p>Participant’s subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate “Overall, this task was:” on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants.</p> <p>Common convention is that average ratings for systems judged easy to use should be 3.3 or above.</p> <p>To measure participants’ confidence in and likability of the [EHRUT] 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.”</p>

4.6 Risk associated to each task

Task Identifier	Task Description	Task Risk
Criteria 170.315(a)(1) - CPOE Medications		
a1.1	Place a new medication order	High
a1.2	Review medication list	Low
a1.3	Access medication order	Low
a1.4	Change medication order	High
a1.5	Review medication list	Low
Criteria 170.315(a)(2) - CPOE Laboratory		
a2.1	Place a new lab order	Medium
a2.2	Review lab orders list	Low
a2.3	Access lab orders	Low
a2.4	Change lab orders	Medium
a2.5	Review lab orders list	Low
Criteria 170.315(a)(3) - CPOE Diagnostic Imaging		
a3.1	Place a new diagnostic imaging order	Medium
a3.2	Review diagnostic imaging order list	Low
a3.3	Access diagnostic imaging order	Low
a3.4	Change diagnostic imaging order	Medium
a3.5	Review diagnostic imaging order list	Low
Criteria 170.315(a)(4) - Drug-drug, Drug-allergy Interaction Checks		
a4.1	Search for patient record	Low
a4.2	Access a medication	Low
a4.3	Review and act on Drug - Allergy check	Medium
a4.4	Review and act on Drug - Drug check	Medium
a4.5	Adjust drug - drug interaction severity level	Low
Criteria 170.315(a)(5) - Demographics		
a5.1	Access patient	Low
a5.2	Record the date of death and the cause of death	Low
a5.3	Enter/change date of birth	Low
a5.4	Enter/change race and ethnicity category	Low
a5.5	Enter/change gender identity and sexual orientation	Low
a5.10	Enter/change patient's preferred language	Low

Task Identifier	Task Description	Task Risk
Criteria 170.315(a)(6) - Problem List		
a6.1	Access patient	Low
a6.2	Review the current problem list	Low
a6.3	Enter a new problem	Medium
a6.4	Review the problem list	Low
a6.5	Make changes to the problem list	Medium
a6.6	Review the changed problem list	Low
Criteria 170.315(a)(7) - Medication List		
a7.1	Access patient	Low
a7.2	Review the current medication list	Low
a7.3	Enter a new medication	High
a7.4	Review the medication list	Low
a7.5	Make changes to the medication list	High
a7.6	Review the changed medication list	Low
Criteria 170.315(a)(8) - Medication Allergy List		
a8.1	Access patient	Low
a8.2	Review the current medication allergy list	Low
a8.3	Enter a new medication allergy	High
a8.4	Review the medication allergy list	Low
a8.5	Make changes to the medication allergy list	High
a8.6	Review the changed medication allergy list	Low
Criteria 170.315(a)(9) - Clinical Decision Support		
a9.1	Access patient	Low
a9.2	Access encounter	Low
a9.3	Review and act on CDS - Problem List	Low
a9.4	Review and act on CDS - Medication List	Low
a9.5	Review and act on CDS - Medication Allergy List	Low
a9.6	Review and act on CDS - Demographics	Low
a9.7	Review and act on CDS - Laboratory	Low
a9.8	Review and act on CDS - Vital Signs	Low
a9.9	Review and act on CDS - Combination(Problem List & Medication List)	Low
a9.10	Activate CDS based on incorporated Medications from TOC	Low
a9.11	Activate CDS based on incorporated Medication Allergies from TOC	Low
a9.12	Activate CDS based on incorporated Problems from TOC	Low

Task Identifier	Task Description	Task Risk
Criteria 170.315(a)(14) - Implantable Device List		
a14.1	Access patient	Low
a14.2	Access Implantable Device List	Low
a14.3	Enter New UDI	Low
a14.4	Access and review information regarding implant	Low
Criteria 170.315(b)(2) - Clinical Information Reconciliation and Incorporation		
b2.1	Browse and view CCDA	Low
b2.2	Display medications from Agastha and outside source	Low
b2.3	Reconcile medications	High
b2.4	Review and validate reconciled list of medications	High
b2.5	Create a file using the CCDA template	Low
b2.6	Display medication Allergies from Agastha and outside source	Low
b2.7	Reconcile medication Allergies	High
b2.8	Review and validate reconciled list of medication Allergies	High
b2.9	Create a file using the CCDA template	Low
b2.10	Display Problem List from Agastha and outside source	Low
b2.11	Reconcile Problem List	High
b2.12	Review and validate reconciled list of Problem List	High
b2.13	Create a file using the CCDA template	Low
Criteria 170.315(b)(3) - E-Prescribing		
b3.1	Access patient	Low
b3.2	Create new prescription(NEWRX)	High
b3.3	Change prescription	High
b3.4	Cancel prescription	Low
b3.5	Refill prescription	High
b3.6	Receive Fill status	Low
b3.7	Request and receive medication history	Low

5. RESULTS

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

The usability testing results for the EHRUT are detailed below (see Table 1). The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance. [Furthermore, the data should be presented in forms such as the table below so that the tasks can be easily identified and their performance results examined and compared.

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

Table 1. Performance and rating data

Measure	N	Task Success	Path Deviation	Task Time		Errors	Task Ratings 5=Easy
				Mean (SD) Sec	Deviations (Observed/Optimal)		
Task	#	%	Deviations (Observed/Optimal)	Mean (SD) Sec	Deviations (Observed/Optimal)	%	Mean (SD)
1. Computerized provider order entry - Medications	10	70%	25/8	225	301/225	30%	4
2. Computerized provider order entry - Laboratory	10	100%	8/5	225	275/225	0%	5
3. Computerized provider order entry - Radiology	10	100%	7/5	225	290/225	0%	5
4. Drug-drug, drug-allergy interaction checks	10	100%	11/5	225	290/225	0%	5

Table 1. Performance and rating data

5. Demographics	10	96%	44/30	325	484/325	4%	4
6. Problem List	10	100%	7/5	225	232/225	0%	5
7. Medication List	10	100%	11/5	225	227/225	0%	5
8. Medication allergy list	10	100%	8/5	225	233/225	0%	5
9. Clinical decision support	10	50%	52/35	375	538/375	50%	2.5
10. Implantable Device	10	75%	45/20	375	512/375	25%	4
11. Clinical information reconciliation	10	79.4%	143/100	525	613/525	20.6%	3.4
12. Electronic prescribing	10	93.3%	9/6	375	455/375	6.7%	4.3

5.1 Results: §170.315(a)(1) Computerized Provider Order Entry (CPOE) – Medications

5.1.1 Data Analysis and Report

Ten (10) participants attempted the CPOE - Medications task. As indicated in Table 1, 70% successfully completed the task. The breakdown was as follows:

- 72% completed A1.1
- 68% completed A1.2

Task Identifier	Task Description
A1.1	The user electronically records a patient’s medication order.
A1.2	The user accesses the patient’s medication order and changes the order

5.1.2 Conclusion

Discussion of the errors

Under this section, we discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

The satisfaction section assessed the rating that the users assigned to the specific task. Satisfaction combined all the tasks to achieve a system level rating.

1. Performance

For some of the users that failed to complete the task, there were noncritical errors related to the navigation. They mostly said that the screen was not intuitive enough for them to get the workflow: Selecting the correct patient and creating the medication. They struggled with some of the labels such as Potency Unit Code and Days supply.

2. Error Analysis

There were critical use errors that were related to the required fields such as prescriber. The system were not set to the defaulted values. The participants expected a warning before they reached the end of the entry portion. This caused some of them not to complete the tasks.

3. Satisfaction

Most users rated the task at 4(Easy) because the errors that they encountered were navigation related.

4. Areas for improvement

The major areas for improvement are as follows:

- Improve the visibility of the New button with a different label and more vibrant colors.
- Improve data validations at the point of data entry.
- Support a faster way for users to correct medication errors.

5.2 Results: §170.315(a)(2) Computerized Provider Order Entry (CPOE) – Laboratory

5.2.1 Data Analysis and Report

Ten (10) participants attempted the CPOE - Laboratory task. As indicated in Table 1, 100% successfully completed the task. The breakdown was as follows:

- 100% completed A2.1
- 100% completed A2.2

A2.1	The user electronically records a patient's laboratory order.
A2.2	The user accesses the patient's laboratory order and changes the order.

5.2.2 Conclusion

Discussion of the errors

Under this section, we discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

The satisfaction section assessed the rating that the users assigned to the specific task. Satisfaction combined all the tasks to achieve a system level rating.

1. Performance

Participants were able to easily navigate to the menu item and complete the task.

2. Error Analysis

There were no critical errors for this task.

3. Satisfaction

All users rated the task at 5(Very Easy).

4. Areas for improvement

The major areas for improvement are as follows:

- Improve the visibility of the New button with a different label and more vibrant colors.
- Support a faster way for users to configure the lab orders.

5.3 Results: §170.315(a)(3) Computerized Provider Order Entry (CPOE) – DiagnosticImaging

5.3.1 Data Analysis and Report

Ten (10) participants attempted the CPOE - Diagnostic Imaging task. As indicated in Table 1, 100% successfully completed the task. The breakdown was as follows:

- 100% completed A3.1
- 100% completed A3.2

Task Identifier	Task Description
A3.1	The user electronically records a patient’s diagnostic imaging order.
A3.2	The user accesses the patient’s diagnostic imaging order and changes the order.

5.3.2 Conclusion

Discussion of the errors

Under this section, we discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using

the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

The satisfaction section assessed the rating that the users assigned to the specific task. Satisfaction combined all the tasks to achieve a system level rating.

1. Performance

Participants were able to easily navigate to the menu item and complete the task.

2. Error Analysis

There were no critical errors for this task.

3. Satisfaction

All users rated the task at 5(Very Easy).

4. Areas for improvement

The major areas for improvement are as follows:

- Improve the visibility of the New button with a different label and more vibrant colors.
- Support a faster way for users to configure the data.

5.4 Results: §170.315(a)(4) Drug-Drug, Drug Allergy Interaction Checks

5.4.1 Data Analysis and Report

Ten (10) participants attempted the Drug-Drug, Drug Allergy Interaction Checks task. As indicated in Table 1, 100% successfully completed the task. The breakdown was as follows:

■ 100% completed A4.1

■ 100% completed A4.2

Task Identifier	Task Description
A4.1	The user enters a medication order using CPOE and is automatically provided: Drug-drug contraindication intervention(s) based on the patient’s medication list prior to completing the order.
A4.2	The user enters a medication order using CPOE and is automatically provided: Drug-allergy contraindication intervention(s) based on the patient’s medication allergy list prior to completing the order.

5.4.2 Conclusion

Discussion of the errors

Under this section, we discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user

interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

The satisfaction section assessed the rating that the users assigned to the specific task. Satisfaction combined all the tasks to achieve a system level rating.

1. Performance

Participants were able to easily navigate to the menu item and complete the task.

2. Error Analysis

There were no critical errors for this task.

3. Satisfaction

All users rated the task at 5(Very Easy).

4. Areas for improvement

The major areas for improvement are as follows:

- Consider the options of breaking down the different alerts by severity and priority to reduce alert fatigue.

5.5 Results: 170.315(a)(5) Demographics

5.5.1 Data Analysis and Report

Ten (10) participants attempted the Demographics task. As indicated in Table 1, 96% successfully completed the task. The breakdown was as follows:

- 100% completed A5.1
- 90% completed A5.2
- 100% completed A5.3
- 100% completed A5.4
- 90% completed A5.5

Task Identifier	Task Description
A5.1	<p>Enable a user to record, change, and access patient demographic data including race, ethnicity, preferred language, sex, sexual orientation, gender identity, and date of birth.</p> <p>(A) Race and ethnicity. (1) Enable each one of a patient’s races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify race. (2) Enable each one of a patient’s ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify ethnicity.</p>
A5.2	<p>(B) Preferred language. Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.</p>
A5.3	<p>(C) Sex. Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1).</p>
A5.4	<p>(D) Sexual orientation. Enable sexual orientation to be recorded in accordance with the standard specified in § 170.207(o)(1) and whether a patient declines to specify sexual orientation.</p>
A5.5	<p>(E) Gender identity. Enable gender identity to be recorded in accordance with the standard specified in § 170.207(o)(2) and whether a patient declines to specify gender identity</p>

5.5.2 Conclusion

Discussion of the errors

Under this section, we discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

The satisfaction section assessed the rating that the users assigned to the specific task. The rating was at the task level and the system level.

1. Performance

Participants were able to easily navigate to the menu item and complete the task. The ones who failed to complete were confused about the label « Language », they were looking for the « Preferred Language « label. Also, some of the participants found the amount of data in the ethnicity, language and race overwhelming.

2. Error Analysis

There were no critical errors for this task.

3. Satisfaction

Most users rated the task at 5 (Very Easy). The ones who rated the task a 4 complained about the amount of data displayed in the Race, Language and Ethnicity sections.

4. Areas for improvement

The major areas for improvement are as follows:

- Suggestion to reduce the amount of data displayed in the Race, Language and Ethnicity fields.

5.6 Results: 170.315(a)(6) Problem List

5.6.1 Data Analysis and Report

Ten (10) participants attempted the Problem List task. As indicated in Table 1, 100% successfully

completed the task. The breakdown was as follows:

- 100% completed A6.1
- 100% completed A6.2

Task Identifier	Task Description
A6.1	The user selects a patient record and accesses the active problem list, which includes entries created over multiple previous encounters and records a new problem.
A6.2	The user accesses the patient’s record for the active problem list, which includes entries for problems entered over multiple encounters and changes the active problem list.

5.6.2 Conclusion

Discussion of the errors

Under this section, we discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

The satisfaction section assessed the rating that the users assigned to the specific task. The rating was at the task level and the system level.

1. Performance

Participants were able to easily navigate to the menu item and complete the task.

2. Error Analysis

There were no critical errors for this task.

3. Satisfaction

All users rated the task at 5(Very Easy).

4. Areas for improvement

The major areas for improvement are as follows:

- No specific area for improvement was identified.

5.7 Results: 170.315(a)(7) Medication List

5.7.1 Data Analysis and Report

Ten (10) participants attempted the Medication List task. As indicated in Table 1, 100% successfully completed the task. The breakdown was as follows:

- 100% completed A7.1
- 100% completed A7.2

Task Identifier	Task Description
A7.1	The user selects a patient record and accesses the active medication list, which includes entries created over multiple previous encounters and records a new medication.
A7.2	The user accesses the patient’s record for the active medication list, which includes entries for medications entered over multiple encounters and changes the active medication list.

5.7.2 Conclusion

Discussion of the errors

Under this section, we discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

The satisfaction section assessed the rating that the users assigned to the specific task. The rating was at the task level and the system level.

1. Performance

Participants were able to easily navigate to the menu item and complete the task.

2. Error Analysis

There were no critical errors for this task.

3. Satisfaction

All users rated the task at 5 (Very Easy).

4. Areas for improvement

The major areas for improvement are as follows:

■ No specific area for improvement was identified.

5.8 Results: 170.315(a)(8) Medication Allergy List

5.8.1 Data Analysis and Report

Ten (10) participants attempted the Medication Allergy List task. As indicated in Table 1, 100% successfully completed the task. The breakdown was as follows:

■ 100% completed A8.1

■ 100% completed A8.2

Task Identifier	Task Description
A8.1	The user selects a patient record and accesses the active medication allergy list that includes entries created over multiple previous encounters and records a new medication allergy.
A8.2	The user accesses the patient's record for the active medication allergy list, which includes entries for medication allergies entered over multiple encounters and changes the active medication allergy list.

5.8.2 Conclusion

Discussion of the errors

Under this section, we discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

The satisfaction section assessed the rating that the users assigned to the specific task. The rating was at the task level and the system level.

1. Performance

Participants were able to easily navigate to the menu item and complete the task.

2. Error Analysis

There were no critical errors for this task.

3. Satisfaction

All users rated the task at 5 (Very Easy).

4. Areas for improvement

The major areas for improvement are as follows:

- No specific area for improvement was identified.

5.9 Results: §170.315(a)(9) Clinical Decision Support

5.9.1 Data Analysis and Report

Ten (10) participants attempted the Clinical Decision Support task. As indicated in Table 1, 50% successfully completed the task. The breakdown was as follows:

- 50% completed A9.1
- 50% completed A9.2

Task Identifier	Task Description
A9.1	<p>The user interacts with the Health IT Module, and clinical decision support (CDS) interventions are provided based on each data element and one combination of the following:</p> <ul style="list-style-type: none"> (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) At least one demographic specified in §170.315(a)(5)(i); (E) Laboratory tests; and (F) Vital signs.
A9.2	<p>The health IT developer demonstrates receiving a transition of care/referral summary to provide CDS interventions based on the incorporated data:</p> <ul style="list-style-type: none"> • Medications; • Medication allergies; and • Problems.

5.9.2 Conclusion

Discussion of the errors

Under this section, we discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

The satisfaction section assessed the rating that the users assigned to the specific task. The rating was at the task level and the system level.

1. Performance

Participants had issues identifying the trigger point for the alert. They found it cumbersome going between the configuration screen and the encounter.

2. Error Analysis

Only half of the participants were able to complete the tasks. The errors were related to the fact that the alerts did not trigger for most of them. For example, one user had to navigate back and forth to change the age before the alert triggered.

3. Satisfaction

All users rated the task at 2.5(Difficult). Participants wanted an easier workflow. For clinical staff, they would like to have a menu from inside the encounters showing them the different triggers.

4. Areas for improvement

The major areas for improvement are as follows:

- Use a point and click option from inside the visit note to display the configuration settings for CDS at the point of data entry.

5.10 Results: 170.315(a)(14) Implantable Device List

5.10.1 Data Analysis and Report

Ten (10) participants attempted the Implantable Device List task. As indicated in Table 1, 75% successfully completed the task. The breakdown was as follows:

- 75% completed A14.1

Task Identifier	Task Description
A14.1	The user records the unique device identifiers for a patient's implantable device in all formats established by the 3 UDI Issuing Agencies.

5.10.2 Conclusion

Discussion of the errors

Under this section, we discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

The satisfaction section assessed the rating that the users assigned to the specific task. The rating was at the task level and the system level.

1. Performance

Participants did not find the screen intuitive. They requested better guidance in the form of tooltips and other help material for novice users.

2. Error Analysis

75% of the participants were able to complete the tasks. The errors were related to the fact that some of the users entered invalid data in the UDI field and there was no validation of the data entered.

3. Satisfaction

All users rated the task at 2(Difficult).

4. Areas for improvement

The major areas for improvement are as follows:

- More guidance needed for the user(tooltip, help icon,...)

5.11 Results: §170.315(b)(2) Clinical Information Reconciliation and Incorporation

5.11.1 Data Analysis and Report

Ten (10) participants attempted the Clinical Information Reconciliation and Incorporation task. As indicated in Table 1, about 75% successfully completed the task. The breakdown was as follows:

- 73% completed B2.1
- 75% completed B2.2
- 73% completed B2.3

Task Identifier	Task Description
B2.1	Enable a user to reconcile the data that represent a patient's active medication list, medication allergy list, and problem list as follows. For each list type: (A). Simultaneously display (i.e., in a single view) the data from at least two sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date;
B2.2	(B). Enable a user to create a single reconciled list of each of the following: medications, medication allergies, or problems;
B2.3	Enable a user to review and validate the accuracy of a final set of data; and
B2.4	(D).Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standard(s): (1) Medications. At a minimum, the version of the standard specified in § 170.207(d)(3); (2) Medication allergies. At a minimum, the version of the standard specified in § 170.207(d)(3); and (3) Problems. At a minimum, the version of the standard specified in § 170.207(a)(4).
B2.5	(E) System verification. Based on the data reconciled and incorporated, the user must be able to create a file formatted according to the standard specified in § 170.205(a)(4) using the Continuity of Care Document template.

- 75% completed B2.4
- 100% completed B2.5

5.11.2 Conclusion

Discussion of the errors

Under this section, we discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

The satisfaction section assessed the rating that the users assigned to the specific task. The rating was at the task level and the system level.

1. Performance

Participants requested better guidance in the form of tooltips and other help material for novice users.

2. Error Analysis

About 79.2% of the participants were able to complete the tasks.

3. Satisfaction

Users rated the task at 3.4(Average).

4. Areas for improvement

The major areas for improvement are as follows:

- Easier access to the import option from the main menu.

5.12 Results: 170.315(b)(3) Electronic Prescribing

5.12.1 Data Analysis and Report

Ten (10) participants attempted the Electronic Prescribing task. As indicated in Table 1, about 93% successfully completed the task. The breakdown was as follows:

- 100% completed B3.1
- 80% completed B3.2
- 80% completed B3.3
- 100% completed B3.4
- 100% completed B3.5

Task Identifier	Task Description
B3.1	(i) Enable a user to perform all the following prescription-related electronic transactions in accordance with the standards specified at § 170.205(b)(2), and, at a minimum, the version of the standard specified in § 170.207(d)(3), as follows: (A) Create new prescriptions (NEWRX);
B3.2	(B) Change prescriptions (RXCHG, CHGRES);
B3.3	(C) Cancel prescriptions (CANRX, CANRES);
B3.4	(D) Refill prescriptions (REFREQ, REFRES);
B3.5	(E) Receive fill status notifications (RXFILL);
B3.6	(F) Request and receive medication history information (RXHREQ, RXHRES).

- 100% completed B3.6

5.12.2 Conclusion

Discussion of the errors

Under this section, we discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

The satisfaction section assessed the rating that the users assigned to the specific task. The rating was at the task level and the system level.

1. Performance

A filter in the Transmit screen caused the system to display a longer list of pharmacies. Which made participants spend more time than usual navigating the screen.

2. Error Analysis

About 93% of the participants were able to complete the tasks.

3. Satisfaction

Participants were satisfied with the workflow. They rated the task an average of 4.3(Easy).

4. Areas for improvement

The major areas for improvement are as follows:

- Suggestion to reduce the number of pharmacies displayed. This is a request that has to do with the temporary filtering issue in the Transmit screen. The Agastha team will look at the causes of the issue.

6. Results: Critical Use Risks for Patient Safety and NISTIR 7741

6.1 Task Mapping

Usability has been a topic of considerable interest in the health IT community. Gans et al. (2005) provided evidence that some frequently cited reasons for lack of adoption of Electronic Health Records (EHRs) – security, privacy, and systems integration – are outranked by productivity and usability concerns.

The ONC 2015 Edition Certification final rule states that the test scenarios used in the summative usability testing be submitted as part of the test results report. The ONC 2015 Edition Companion Guide for Safety-Enhanced Design - 45 CFR 170.315(g)(3) includes a preamble/clarification that user-centered design(UCD) processes be applied in order to satisfy this certification criterion. It is also recommended that the test scenarios be based upon an analysis of critical use risks for patient safety, which can be mitigated or eliminated by improvements to the user interface design.

In addition, the Companion Guide for Safety-Enhanced Design advises health IT developers to select an industry standard process to be employed for UCD, including NISTIR 7741: NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records.

It was noted that health IT developers be allowed to perform many iterations of the usability testing, but the submission that is ultimately provided for summative usability testing and certification must be an expression of a final iteration, and the test scenarios used would need to be submitted as part of the test results.

As part of the task construction, tasks were designed by Agastha and informed by NISTIR 7741. Findings associated with critical use risks identified via Agastha are reported within the results. As part of setting up scenarios to assess Identification of Information, the usability test team used NISTIR 7741 to inform usability test task creation.

6.2 Task Participant and Instructions

Based on user characteristics, typical workflow, and tasks performed as part of their daily work, the clinical users (providers and nurses) attempted multiple tasks that called for the provider and nurse to select a specific patient from a patient list. Participants were given the patient names orally and via a sheet that was available to the participant throughout the usability test tasks.

Provider and nurses were interrupted and asked to do other tasks such as pull up a medication while completing a usability test task. After providing the information, the usability test returned to the task at hand. Provider and nurse data were combined based on the fact that neither the task nor the user characteristics differed based on these interruptions.

6.3 Data Analysis and Reporting

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. Providers and nurses selected were given the patient names orally and via a patient list within the context of each usability test tasks.

During Scenario 1((a)(1) - CPOE Medications), 100% of participants correctly selected the patient to order medications.

During Scenario 2((a)(2) - CPOE Laboratory and (a)(3) - CPOE Radiology), 100% of participants correctly selected the patient to place laboratory orders and diagnostic imaging.

During Scenario 3((a)(5) - Demographics), 100% of participants correctly selected the patient to add and change the date and cause of death.

During Scenario 4((a)(6) - Problem List), 80% of participants correctly selected the patient to add and change the problem list and the medication allergy.

During Scenario 5(Criteria 170.315(a)(9) - Clinical Decision Support), 50% of participants successfully completed ordering vital signs on the correct patient to identify source attributes for CDS resources.

During Scenario 6((a)(14) - Implantable Device List). 100% of participants successfully accessed the patient chart to enter an implantable device.

During Scenario 7((b)(2) - Clinical Information Reconciliation and Incorporation), 90% of participants correctly selected the patient to interact with clinical information reconciliation of medication allergies, problems, and medications.

During Scenario 8 ((b)(3) - E-Prescribing), 100% of participants correctly selected the patient to create an electronic prescription.

6.4 Discussion of the Findings

The following sections discuss the results based on four perspectives: performance, error analysis, satisfaction and areas for improvement.

Performance, user errors and other issues resulting from task failures are discussed in the Performance section. Noncritical system issues related to efficiency are also discussed in the Performance section. The overall effectiveness was measured with task success and failure using the effectiveness metrics. The associated recommendations are provided in the Areas for Improvement section.

The error analysis section relates to the identification of user errors and user interface design issues as well as the classification of severity related to the effects of the error. User errors and user interface design issues that resulted in task failures or that are known industry risk issues are considered more severe compared to noncritical system usability issues related to efficiency.

Therefore, the analysis of more serious errors and issues is provided in the Error Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

PERFORMANCE

Performance of selecting the correct patient was above the 95% success criterion for most tasks. Performance following interruptions was below the 95% success criterion.

ERROR ANALYSIS

Compilation of data from this UCD test will be used to focus future development and training on areas where there may be potential for user error which could result in a risk of patient safety or a loss of physician efficiency. Observations during the Usability Review determined the following user errors labeled « **Potential Patient Safety Issue** » that could negatively impact patient safety:

Risk Assessment

Measure	Error Analysis
1. Computerized provider order entry - Medications	<ul style="list-style-type: none"> Some participants struggled to select the correct patient when multiple records of patients with similar attributes were listed(Potential patient safety issue). Some participants struggled with the labels Potency Unit Code and days Supply(Potential patient safety issue). The New button to create the medication was not easy to find for some users.
2. Computerized provider order entry - Laboratory	<ul style="list-style-type: none"> No patient safety concerns observed.
3. Computerized provider order entry - Radiology	<ul style="list-style-type: none"> No patient safety concerns observed.
4. Drug-drug, drug-allergy interaction checks	<ul style="list-style-type: none"> No patient safety concerns observed.
5. Demographics	<ul style="list-style-type: none"> Some participants were confused about the language label versus preferred language label. Participants found the amount of data in the Ethnicity, Race and Language overwhelming. No patient safety concerns observed.
6. Problem List	<ul style="list-style-type: none"> No patient safety concerns observed.
7. Medication List	<ul style="list-style-type: none"> No patient safety concerns observed.
8. Medication allergy list	<ul style="list-style-type: none"> No patient safety concerns observed.
9. Clinical decision support	<ul style="list-style-type: none"> Users wanted an easier workflow with a way to select and change triggers from inside the visit note(Potential patient safety issue). Alerts did not trigger for some users because of the popup blocker.
10. Implantable Device	<ul style="list-style-type: none"> Users clicked Ok to save but there was no immediate confirmation.
11. Clinical information reconciliation	<ul style="list-style-type: none"> Most participants needed help with the workflow but could not easily access help material and tooltips(Potential patient safety issue).
12. Electronic prescribing	<ul style="list-style-type: none"> A filter in the Transmit screen caused the system to display a longer list of pharmacies. Participants complained about the length of time to complete this task.

SATISFACTION

Satisfaction levels were rated at the scenario level and later combined for the final tally at the system level.

AREAS FOR IMPROVEMENT

We express a deep commitment to the development and provision of a safe and effective EHR. Our critical risk assessment have to do with the tracking, identifying and addressing patient safety issues related to the use of Agastha Enterprise Healthcare Software.

Performance of the CPOE - Medications, Clinical Decision Support, Implantable Device, Clinical Information Reconciliation and electronic Prescribing fell below the 95% success criterion. However, the participants did not express shortcomings in the lack of adherence to safety guidelines.

Addressing the critical risks issues with patient identification, Agastha consistently displays information critical to patient identification in a specific area on the patient banner. The information is displayed in the same location whether the user navigates to different screens in the EHR.

Critical information for patient identification includes:

- ◆ The Chart and account numbers are displayed first
- ◆ The patient's name is shown in the format First Name followed by Last Namer e.g., John Doe
- ◆ The date of birth is shown followed by the age in parentheses e.g., 02/01/1945(72)
- ◆ The patient phone number is displayed in the format(xxx)xxx-xxxx
- ◆ The patient picture is also shown in the banner

In addition, Agastha expresses an interest in an independent body guiding the development of usability standards and we would like to also be involved with the development and sharing of industry best practices, guidelines, templates regarding safety-enhanced design.

7 System Satisfaction

7.1 About System Usability Scale (SUS) Scores

Participants completed the System Usability Scale (SUS) questionnaire at the end of their session. The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

7.2 Clinical System Satisfaction Results

2 providers, 4 nurses and 6 other users completed the SUS questionnaire at the end of their session. The system scored an average of 81 based on 4 nurses and scored an average of 75 based on 2 provider responses.

7.3 Configuration System Satisfaction Results

2 configuration participants completed the SUS questionnaire at the end of their session. The system scored an average of 79 based on their responses.