§170.315(g)(3)—Safety-enhanced Design: System Usability Report

EHR Usability Test Report of Capella EHR v6.1

2015 Edition - Meaningful Use Stage 3

§170.315(g)(3) –Safety-enhanced Design

Report based on Common Industry Format for Usability Test Reports

Date of Usability Test: 12/20/2017

Topic	Details
Version	Capella EHR 6.1
Date of Usability Test	12/20/2017
Date of Report	01/15/2018
Report Prepared by	Acurus Solutions

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Part I: UCD Process Applied

NIST 7741 UCD processes was applied during the creation of the software for the below criteria to ensure the designed EHR is efficient, effective, and satisfying to the user

- § 170.315 (a)(1) Computerized Provider Order Entry (CPOE) medications
- § 170.315 (a)(2) CPOE laboratory
- § 170.315 (a)(3) CPOE diagnostic imaging
- § 170.315 (a)(4) Drug-drug, Drug-allergy Interaction Checks for CPOE
- § 170.315 (a)(5) Demographics
- § 170.315 (a)(6) Problem List
- § 170.315 (a)(7) Medication List
- § 170.315 (a)(8) Medication Allergy List
- § 170.315 (a)(9) Clinical Decision Support
- § 170.315 (a)(14) Implantable Device List
- § 170.315 (b)(2) Clinical Information Reconciliation and Incorporation
- § 170.315 (b)(3) Electronic Prescribing

Executive Summary

A usability test of Capella-EHR V6.1, a web based EHR system, was conducted on 12/20/2017 in the clinician's office in Pomona, CA. Software department of Acurus Solutions Inc. conducted the study. 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 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:

- Ordering a Medication
- Ordering a Laboratory test
- Ordering a diagnostic imaging test
- Perform drug-drug interaction checks
- Perform drug-allergy interactive checks
- Access patient demographics
- Access Medication list for a patient
- Access Medication Allergy list for a patient
- Activate Clinical Decision Support interventions
- Add an implantable device record to a patient
- Perform clinical reconciliation for Transition of Care
- Prescribe a medication and transmit to pharmacy

Number of Test Participants - 10

This study was performed on the below capabilities of Capella EHR v6.1,

- 1. § 170.315 (a)(1) Computerized Provider Order Entry (CPOE) medications
- 2. § 170.315 (a)(2) CPOE laboratory
- 3. § 170.315 (a)(3) CPOE diagnostic imaging

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- 4. § 170.315 (a)(4) Drug-drug, Drug-allergy Interaction Checks for CPOE
- 5. § 170.315 (a)(5) Demographics
- 6. § 170.315 (a)(6) Problem List
- 7. § 170.315 (a)(7) Medication List
- 8. § 170.315 (a)(8) Medication Allergy List
- 9. § 170.315 (a)(9) Clinical Decision Support
- 10. § 170.315 (a)(14) Implantable Device List
- 11. § 170.315 (b)(2) Clinical Information Reconciliation and Incorporation
- 12. § 170.315 (b)(3) Electronic Prescribing

During the 150- minute, one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form they were instructed that they could withdraw at any time. The participants have prior experience with EHR. 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 recorded user performance data on paper. The administrator did not give the participant assistance on how to complete the task. The participants were given training prior to each module that was tested. The administrator read a script to the participants while the participant followed along on the EHR. After training was completed, the administrator asked if they had any questions, or needed to see any features of the module again. After that, the administrator gave the participants the test item associated with the module. The participants were instructed to read over the test item and indicate if anything was unclear. The following types of data were collected for each participant:

- 1. Number of tasks successfully completed within the allotted time without assistance
- 2. Time to complete the tasks
- 3. Number and types of errors
- 4. Path deviations
- 5. Participant's verbalization
- 6. Participant's satisfaction ratings of the system All participants' data were 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. 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.

Task\Measure	#	Task Success	Path Deviation	Task Time (in seconds)		Errors	Task Ratings (Likert Scale)
		Mean % (SD %)	Deviations (Observed /Optimal)	Mean (SD)	Deviations (Observed /Optimal)	Mean% (SD %)	Mean (SD)
CPOE- Medication	10	100(0)	21/15	169.80 (21.73)	170/120	0.80 (0.63)	4.60 (0.32)
CPOE- Labs	10	100(0)	18/15	168.30 (21.36)	168/120	0.90 (0.74)	4.55 (0.37)
CPOE- Diagnostic imaging	10	100(0)	26/23	147.60 (3.10)	148/120	0.30 (0.48)	4.85 (0.24)

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Task\Measure	#	Task Pa Success	Path Deviation	Task Time (in seconds)		viation Task Time (in sec		Errors	Task Ratings (Likert Scale)
		Mean % (SD %)	Deviations (Observed /Optimal)	Mean (SD)	Deviations (Observed /Optimal)	Mean% (SD %)	Mean (SD)		
Drug-drug, Drug-allergy Interaction Checks	10	100(0)	13/12	169.10 (21.77)	169/120	0.20 (0.42)	4.90 (0.21)		
Demographics	10	100(0)	8/7	59.00 (4.11)	59/40	0.00 (0.00)	5.00 (0.00)		
Problem List	10	100(0)	9/7	65.00 (4.11)	65/40	0.30 (0.48)	4.85 (0.24)		
Medication List	10	100(0)	11/7	89.00 (4.11)	89/60	0.70 (0.82)	4.65 (0.41)		
Medication Allergy List	10	100(0)	8/7	87.40 (4.22)	87/60	0.00 (0.00)	0.00 (0.00)		
Clinical Decision Support	10	100(0)	22/19	223.00 (4.22)	223/180	1.00 (0.82)	4.50 (0.41)		
Implantable Device List	10	100(0)	13/9	296.80 (8.48)	297/220	1.40 (0.52)	4.30 (0.26)		
Clinical Information Reconciliation and Incorporation	10	100(0)	16/12	202.90 (6.05)	203/180	0.60 (0.70)	4.70 (0.35)		
Electronic Prescribing	10	100(0)	24/23	414.80 (8.82)	415/360	1.10 (0.57)	4.45 (0.28)		

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

1. Major findings:

Participant finds overall system is user friendly and easy to use.

Some participants aren't used to web hosted software. They don't click "Save" button before leaving current screen.

2. Areas for improvement:

Lab and Imaging orders can be available in separate forms User should have the access to add and modify the rule

Introduction

The EHRUT tested for this study was the web-based application **Capella-EHR V6.1**. Designed to present medical information to the healthcare providers in an ambulatory setting across multiple specialties (Internal Medicine, Family Medicine etc..), the EHRUT consists of 13 tabs meant to divide the system into specific roles in standard private practice offices; The EHRUT consists of SOAP charting, electronic prescribing of medicine, lab ordering, etc. The usability testing attempted to represent realistic exercises and conditions.

Intended Users –Providers and Clinical Staff members of practices in ambulatory setting across multiple specialties (Internal Medicine, Family Medicine etc..).

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 Capella-EHR. To this end, measures of effectiveness,

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efficiency and user satisfaction, such as timing tasks, usability questionnaire, error reporting, and participant comments, were captured during the usability testing.

Methodology

Participants

A total of 10 participants were tested on the EHRUT. Participants in the test were a Medical Doctor, Nurse Practitioner, Office Manager and Medical Assistant. Participants were recruited by Acurus Solutions Inc. sales representatives and were compensated for their time. In addition, the participants had no direct connection to the development of or organization producing the EHRUT(s). Participants were not from the testing or supplier organization. Participants were given the opportunity to have the same orientation level of training as the actual end users would have received.

Recruited participants had a mix of backgrounds and demographic characteristics. The following is a table of participants by characteristics, including demographics, professional experience, computing experience, and user needs for Assistive Technology (AT). Participant names were replaced with participant IDs so that an individual's data cannot be tied back to individual identities

Part	Gender	Age	Age	Education	Occupation/Rol	Professional	Computer	Capella-EHR	Assistive
ID			Range		е	Experience	Experience in	Product	Technology
						(Current	Months	Experience	Needs
						Position) in		in Month	
						Months			
01	Male	54	50-59	Medical	MD, Eligible	240	250	0	None
				Doctor	Provider				
02	Female	51	50-59	Medical	MD, Eligible	180	230	0	None
				Doctor	Provider				
03	Male	40	40-49	Nurse	NP, Eligible	120	150	0	None
				Practitioner	Provider				
04	Female	32	30-39	Nurse	NP, Eligible	72	110	0	None
				Practitioner	Provider				
05	Male	31	30-39	Nurse	NP, Eligible	48	86	0	None
				Practitioner	Provider				
06	Male	58	50-59	Respiratory	Office Mgr	240	270	0	None
				Therapist					
07	Female	31	30-39	MA	Medical	84	134	0	None
					Assistant				
08	Male	26	20-29	MA	Ultrasound	60	110	0	None
					Tech				
09	Female	24	20-29	MA	Medical	36	86	0	None
					Assistant				
10	Male	22	20-29	MA	Medical	24	74	0	None
					Assistant				

Ten (10) participants were recruited and all of them participated in the usability test. Zero participants failed to show for the study. Participants were tested individually and were scheduled for one session in which all modules were trained and tested.

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Tasks

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

- 1. Ordering a Medication
- 2. Ordering a Laboratory test
- 3. Ordering a diagnostic imaging test
- 4. Perform drug-drug interaction checks
- 5. Perform drug-allergy interactive checks
- 6. Access patient demographics
- 7. Access Medication list for a patient
- 8. Access Medication Allergy list for a patient
- 9. Activate Clinical Decision Support interventions
- 10. Add an implantable device record to a patient
- 11. Perform clinical reconciliation for Transition of Care
- 12. Prescribe a medication and transmit to pharmacy

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

Procedures

Participants were instructed to perform the tasks as specific instructions below

- 1. As quickly as possible; however, accuracy is more important than speed on the tasks.
- 2. Without assistance; administrators were 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 participant indicated that they were ready. The task time was stopped once the participant indicated that they had successfully completed the task.

Following the session, the administrator gave each participant the post-test questionnaire and thanked everyone for their participation

Test Locations

The test location was on-site at the participants' medical practice/clinic where they work. Only the participant and administrator were in the test room. Because of the demand of work, the administrator set up a time for each participant as opposed to gathering all of them in one area all at the same time. Audio levels and distractions were kept to a minimum at an assigned room. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

Test Environment

The testing was conducted at a provider's facility in a designated room. For testing, the computers ran Windows 7 as an operating system. The participants used the same computer, a mouse when using the EHR and were seated properly in a room where outside noise is controlled and kept to a minimum. The environment is setup with Display Monitor size of 19inch with screen resolution 1280 X 1024. The systems were connected to internet using High-Speed LAN. The application was set up by Acurus Solutions Inc. according to the vendor's documentation describing system set-up and preparation. The

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application was running on server setup using a test database. 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 magnification of the browser size)

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

Data Scoring

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

Measures	Rationale and Scoring
Effectiveness: Task	A task was counted as a "Success" if the participant was able to achieve the
Success	correct outcome, without assistance, within the time allotted on a per task
	basis.
	The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.
	Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency. Optimal task performance time, as bench-marked 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.
Effectiveness: Task	If the participant abandoned the task, did not reach the correct answer or
Failures	performed it incorrectly, or reached the end of the allotted time before
	successful completion, the task was counted as a "Failures." No task times
	were taken for errors.
	The total number of errors was calculated for each task and then divided by
	the total number of times that task was attempted. Not all deviations would

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Measures	Rationale and Scoring
	be counted as errors. This should also be expressed as the mean number of
	failed tasks per participant.
Efficiency: Task	The participant's path (i.e., steps) through the application was recorded.
Deviations	Deviations occur if the participant, for example, went to a wrong screen,
	clicked on an incorrect menu item, followed an incorrect link, or interacted
	incorrectly with an on-screen control. This path was compared to the optimal
	path. The number of steps in the observed path is divided by the number of
	optimal steps to provide a ratio of path deviation. It is strongly recommended that task deviations be reported.
	Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.
Efficiency: Task Time	Each task was timed from when the administrator said "Begin" until the
	participant said, "Done." If he or she failed to say "Done," the time was
	stopped when the participant stopped performing the task. Only task times
	for tasks that were successfully completed were included in the average task
	time analysis. Average time per task was calculated for each task. Variance
	measures (standard deviation and standard error) were also calculated.
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was
	measured by administering both a simple post-task question as well as a post-
	session questionnaire. After each task, the participant was asked to rate
	"Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These
	data are averaged across participants. Common convention is that average
	ratings for systems judged easy to use should be 3.3 or above.
	To measure participants' confidence in and likeability of the Capella-EHR V5.4
	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."

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 in below table. The results should be seen in light of the objectives and goals outlined in Section Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance.

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		Task Success	Path Deviation	Task Time (in seconds)		Errors	Task Ratings (Likert Scale)
Task\Measure	#	Mean % (SD %)	Deviations (Observed /Optimal)	Mean (SD)	Deviations (Observed /Optimal)	Mean% (SD %)	Mean (SD)
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CPOE- Labs	10	100(0)	18/15	168.30 (21.36)	168/120	0.90 (0.74)	4.55 (0.37)
CPOE- Diagnostic imaging	10	100(0)	26/23	147.60 (3.10)	148/120	0.30 (0.48)	4.85 (0.24)
Drug-drug, Drug- allergy Interaction Checks	10	100(0)	13/12	169.10 (21.77)	169/120	0.20 (0.42)	4.90 (0.21)
Demographics	10	100(0)	8/7	59.00 (4.11)	59/40	0.00 (0.00)	5.00 (0.00)
Problem List	10	100(0)	9/7	65.00 (4.11)	65/40	0.30 (0.48)	4.85 (0.24)
Medication List	10	100(0)	11/7	89.00 (4.11)	89/60	0.70 (0.82)	4.65 (0.41)
Medication Allergy List	10	100(0)	8/7	87.40 (4.22)	87/60	0.00 (0.00)	0.00 (0.00)
Clinical Decision Support	10	100(0)	22/19	223.00 (4.22)	223/180	1.00 (0.82)	4.50 (0.41)
Implantable Device List	10	100(0)	13/9	296.80 (8.48)	297/220	1.40 (0.52)	4.30 (0.26)
Clinical Information Reconciliation and Incorporation	10	100(0)	16/12	202.90 (6.05)	203/180	0.60 (0.70)	4.70 (0.35)
Electronic Prescribing	10	100(0)	24/23	414.80 (8.82)	415/360	1.10 (0.57)	4.45 (0.28)

System Usability Test

Participant	System Usability Test Results
MD1	67.5%
MD2	62.5%
NP1	65%
NP2	70%
NP3	87.5%
OM	62.5%
MA1	67.5%
MA2	65%
MA3	72.5%
MA4	67.5%

The System Usability Test Scale (SUS) scored the subjective satisfaction with the system based on performance with these tasks to be: 68.75%.

Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average

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Discussion on the Findings

Effectiveness

Success was achieved in every outcome of this study; however, there were some path deviations, particularly during the e-prescribing module. This suggests that parts of the e-prescribing module are not intuitive or user friendly, even after being fully trained on it.

Efficiency

Optimal time for each task was not met by any participant. There seems to be a disconnect between experts who know how to use the system and those that do not. Most of the time taken for each participant was because they were searching for the next button to click on or the next field to fill out. Again, this suggests that the intuitiveness of the Capella-EHR can be improved

Satisfaction

Overall participants are satisfied with the technology used in the EHRUT that makes the software user friendly.

Major Findings

- 1. Participant finds overall system is user friendly and easy to use.
- 2. Some participants aren't used to web hosted software. They don't click "Save" button before leaving current screen.

Areas of Improvements

- 1. Lab and Imaging orders can be available in separate forms
- 2. User should have the access to add and modify the rule

Appendices

Effectiveness measurement Table

		Success Rating		
Task\Measure	Easily completed	Completed with difficulty or help	Not completed	Comments
CPOE- Medication				
CPOE- Labs				
CPOE- Diagnostic imaging				
Drug-drug, Drug-allergy				
Interaction Checks				
Demographics				
Problem List				
Medication List				
Medication Allergy List				
Clinical Decision Support				

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		Success Rating		
Task\Measure	Easily completed	Completed with difficulty or help	Not completed	Comments
Implantable Device List				
Clinical Information Reconciliation and Incorporation				
Electronic Prescribing				

Efficiency Measurement Table

Task\Measure	Time Taken	Comments
CPOE- Medication		
CPOE- Labs		
CPOE- Diagnostic imaging		
Drug-drug, Drug-allergy Interaction		
Checks		
Demographics		
Problem List		
Medication List		
Medication Allergy List		
Clinical Decision Support		
Implantable Device List		
Clinical Information Reconciliation and		
Incorporation		
Electronic Prescribing		

Overall rating of the tasks

Task\Measure	Very Difficult				Very Easy
CPOE- Medication					
	1	2	3	4	5
CPOE- Labs					
	1	2	3	4	5

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Task\Measure	Very Difficult				Very Easy
CPOE- Diagnostic imaging					
	1	2	3	4	5
Drug-drug, Drug-allergy Interaction Checks					
interaction checks	1	2	3	4	5
Demographics					
	1	2	3	4	5
Problem List					
	1	2	3	4	5
Medication List					
	1	2	3	4	5
Medication Allergy List					
	1	2	3	4	5
Clinical Decision Support					
	1	2	3	4	5
Implantable Device List					
	1	2	3	4	5
Electronic Prescribing					
	1	2	3	4	5
Clinical Information					
Reconciliation and Incorporation	1	2	3	4	5
	1	2	3	4	5

System Usability Scale Questionnaire

#	Question	Strongly disagree				Strongly agree
1	I think that I would like to use this system					
	frequently	1	2	3	4	5
2	I found the system unnecessarily complex					
		1	2	3	4	5
3	I thought the system was easy to use					
		1	2	3	4	5
4	I think that I would need the support of a					
	technical person to be able to use this system	1	2	3	4	5

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#	Question	Strongly disagree				Strongly agree
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

Steps to complete the task

CPOE (Computerized Provider Order Entry)

Lab Order

- a. Select EMR from the top menu
- b. Slide mouse to CPOE(Order) from the list displayed for EMR
- c. Click on Create Order from the options available for CPOE(Order)
- d. Type First and Last Name of Patient
- e. Click on Search to search the patient
- f. Select a patient by double clicking the particular line item
- g. Physician Select a physician from the list of physicians available
- h. Select a Lab centre from the list displayed when we click on the combo box of Lab
- i. Select a Bill Type.
- j. Fill in Collection Date
- k. Select Specimen
- I. Enter Quantity
- m. Select Units
- n. Select the Diagnosis
- o. Select the Procedures to be tested
- p. Click on Save and Submit

Image Order

- a. Select EMR from the top menu
- b. Slide mouse to CPOE(Order) from the list displayed for EMR
- c. Click on Create Order from the options available for CPOE(Order)
- d. Type First and Last Name of Patient
- e. Click on Search to search the patient

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- f. Select a patient by double clicking the particular line item
- g. Physician Select a physician from the list of physicians available
- h. Select a Image center from the list displayed when we click on the combo box of Lab
- i. Select a Bill Type.
- j. Fill in Collection Date
- k. Select Specimen
- I. Enter Quantity
- m. Select Units
- n. Select the Diagnosis
- o. Select the Procedures to be tested
- p. Click on Save and Submit

E-Prescription

- a. Select EMR from the top menu
- b. Click on E-Prescription from the options available under EMR
- c. Type First and Last Name of Patient
- d. Click on Search to search the patient
- e. Select a patient by double clicking the particular line item
- f. Select a pharmacy
- g. Add the Medication Allergies
- h. Enter the reactions for the allergy
- i. Click on Done with Allergies
- j. Prescribe the medication from the list or by searching the medication
- k. Enter the Signature Password
- I. Click on Send to send the medication to the pharmacy
- m. Drug-allergy, Drug-drug interaction check
- n. Select EMR from the top menu
- o. Click on E-Prescription from the options available under EMR
- p. Type First and Last Name of Patient
- q. Click on Search to search the patient
- r. Select a patient by double clicking the particular line item
- s. Select a pharmacy
- t. Add the Medication Allergies
- u. Enter the reactions for the allergy
- v. Click on Done with Allergies
- w. Prescribe the medication from the list or by searching the medication
- x. Prescribe a medication that is in interaction with the previous drug entry
- y. Check for the Drug-Drug interaction warning message within the Erx interface of Dr.First Rcopia
- z. Prescribe a medication that the patient is allergic to (which you have added in point viii)
- aa. Check for the Drug-Allergy interaction warning message within the Erx interface of Dr.First Rcopia

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Drug-allergy, Drug-drug interaction check

- a. Select EMR from the top menu
- b. Click on E-Prescription from the options available under EMR
- c. Type First and Last Name of Patient
- d. Click on Search to search the patient
- e. Select a patient by double clicking the particular line item
- f. Select a pharmacy
- g. Add the Medication Allergies
- h. Enter the reactions for the allergy
- i. Click on Done with Allergies
- j. Prescribe the medication from the list or by searching the medication
- k. Prescribe a medication that is in interaction with the previous drug entry
- Check for the Drug-Drug interaction warning message within the Erx interface of Dr.First Rcopia
- m. Prescribe a medication that the patient is allergic to (which you have added in point viii)
- n. Check for the Drug-Allergy interaction warning message within the Erx interface of Dr.First Rcopia

Demographics

- o. Select Patient from the top menu
- p. Click on Demographics from the options available under Patient
- q. Type First and Last Name of the patient in the Capella Find Patient window
- r. Select the correct patient from the list of suggestions based on the search criteria
- s. Click on OK button to open the patient Demographics

Problem List

- t. Select EMR from the top menu
- u. Click on Manage Problem List from the options available under EMR
- v. Type First and Last Name of the patient in the Capella Find Patient window
- w. Now, Manage Problem List window will get opened for the patient
- x. You can add any ICD as problem for the patient and set status along with start and end date of the problem condition for the patient
- y. Click on Save button to save the changes
- z. Click on Close button to close the Manage Problem List

Medication List

- a. Select EMR from the top menu
- b. Click on E-Prescription from the options available under EMR
- c. Type First and Last Name of Patient
- d. Click on Search to search the patient
- e. Select a patient by double clicking the particular line item
- f. Click on Manage Medications link at the top of the Dr. First Rcopia User Interface
- g. Now you can view the list of medications for the patient

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h. You can either modify or stop any existing medication for the patient

Medication Allergy List

- a. Select EMR from the top menu
- b. Click on E-Prescription from the options available under EMR
- c. Type First and Last Name of Patient
- d. Click on Search to search the patient
- e. Select a patient by double clicking the particular line item
- f. Click on Manage Allergies link at the top of theDr. First Rcopia User Interface
- g. Now you can view the list of medication allergies for the patient
- h. You can either inactivate or modify or delete any existing medication allergy for the patient

Clinical Decision Support

- a. Select Utilities from top menu
- b. Slide mouse to Office management from the list displayed for Utilities
- c. Click on Manage CDS from the options available for Office management
- d. Select the required rules for a user and click update.
- e. Select EMR from top menu
- f. Select Enter Vitals in EMR Menu
- g. Find patient screen will open
- h. Enter data in any search criteria
- i. Click search
- j. Select the patient from grid and click ok.
- k. Enter vitals screen will open
- I. For Diabetes management based on Hemoglobin A1c Rule,
 - a. Patient age is between 18 and 75
 - b. Enter HbA1c level > 7%
 - c. Click on save
 - d. Notification/Alert should show
- m. For High blood pressure management Rule
 - a. Enter BP more than 140/90 mm Hg
 - b. Click save
 - c. Notification/Alert should show.
- n. For Low Density Lipoprotein (LDL) Management Rule
 - a. Enter LDL more than 100mg/dl
 - b. Click on save
 - c. Notification/Alert should show

Implantable Device List

- a. Select a patient encounter from MyQ
- b. Process the encounter by clicking on the Process Encounter button or by double-clicking the encounter in MyQ
- c. Click on the Orders Tab
- d. Click on the Procedures Sub Tab

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- e. Optional: Select a CPT from the Manage Frequently used Procedures
- f. Under the Implantable Device section, enter the UDI/DI given in the test data as per the standard
- g. Click on the Find button, the values related to the Device ID/ UDI will get populated in the below fields
- h. Choose the status either Active / Inactive from the drop-down box located next to the Find button
- i. Click on Add button to add the device to the patient record
- j. Under the procedure section, you will be able to see all the active devices by default.
- k. To see inactive devices, please click on the Show all check box located just below the clear all button of the implantable device section
- I. You can edit the entries by clicking on the Edit Icon located corresponding to the device in the procedure section
- m. You can delete the entries by clicking on the Delete Icon located corresponding to the device in the procedure section

Clinical Information Reconciliation

- a. Add some Medication and Allergy in ERX
- b. Add some Problem list in Manage Problem list
- c. Click Exchange @Clinical Exchange @Import
- d. Alternate iii: Click on the clinical exchange link from the short cut bar
- e. This opens the Import window. Click on the Refresh CCD Mail box button to get your CCD file
- f. Select the CCDA file and click on the View button
- g. The view button will open up the human readable format of the received CCD
- h. Click on the Reconcile button located at the bottom of the view window
- Merge existing content in EHR and the Incorporated CCD for the sections Medications,
 Medication Allergies and Problem List
- j. Click on the save button
- k. Select the same patient from EMR →Open Patient Chart
- I. In the patient summary bar, you can see the Merged Medications, Medication Allergies and Problems for the patient

E Prescribing

- a. Select EMR from the top menu
- b. Click on E-Prescription from the options available under EMR
- c. Type First and Last Name of Patient
- d. Click on Search to search the patient
- e. Select a patient by double clicking the particular line item
- f. Select a pharmacy
- g. Add the Medication Allergies
- h. Enter the reactions for the allergy
- i. Click on Done with Allergies
- j. Prescribe the medication from the list or by searching the medication

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- k. Enter the Signature Password
- I. Click on Send to send the medication to the pharmacy

Optimal Path to complete the task

CPOE (Computerized Provider Order Entry)

Lab Order

EMR→CPOE(Order)→Create Order→Search for the patient→Select the Patient→Select
Physician→Select Lab center→Select Bill Type→Fill in Collection date→Select Specimen→Enter
Quantity→Select Units→Select Diagnosis→Select Procedures→Click "Save and Submit"

Image Order

EMR→CPOE(Order→Create Order→Search for the patient→Select Patient→Select
Physician→Select Image center→Select Bill Type→Fill in Collection date→Select Specimen→Enter
Quantity→Select Units→Select Diagnosis→Select Procedures→Click "Save and Submit"

Medication

EMR→E-Prescription→Search for the patient→Select Patient→Select Pharmacy→Add allergies→Add Reactions→Click on Done with Allergies→Enter the medication to search→Click on Find→Select medication→Check Drug interactions→Capture Sig→Select duration→Select Quantity→Select Refills→Capture Directions to Pharmacist→Enter directions to patient→Click on continue→Capture stop medication details→Click Ok→Sign the medication→Click on Send

Drug-Allergy, Drug-drug interaction checks

EMR→E-Prescription→Search for the patient→Select Patient→Select Pharmacy→Add allergies→Add Reactions→Click on Done with Allergies→Enter the medication to search→Click on Find→Select medication→Check Drug-Drug, Drug-Allergy interactions

Demographics

Patient→Demographics→Search for the patient→Select Patient→View Patient Demographics→Perform Modifications as per test data→Click on Save

Problem List

EMR→Manage Problem List→Search for the patient→Select Patient→View Patient Problem List→Perform Modifications as per test data→Click on Save

Medication List

EMR→E-Prescription→Search for the patient→Select Patient→Click on Manage Medication→View List of Medications→Modify the status of the medication

Medication Allergy List

EMR→E-Prescription→Search for the patient→Select Patient→Click on Manage Allergy→View List of Medications→Modify the status of the medication

Clinical Decision Support

Utilities→Office Management→Manage CDS→Select required rules→Click

Update→ClickClose→EMR→Enter Vitals→Search for the patient→Select diabetic Patient→Enter

HbA1c level > 7%→Click Save→Notification/Alert should show→Enter BP more than 140/90 mm

Hg→Click Save→Notification/Alert should show→Enter LDL more than 100mg/dl→Click

Save→Notification/Alert should show

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Implantable Device List

MyQ \rightarrow Select Encounter \rightarrow Process Encounter \rightarrow Click on Order Tab \rightarrow Click on Procedure Subtab \rightarrow Enter the UDI/DI in the implantable device section \rightarrow Click on Find button \rightarrow Choose status (Active/Inactive) \rightarrow Click on Add

Clinical Information Reconciliation

ERX \rightarrow Add Medication \rightarrow Prescribe \rightarrow Add Allergy \rightarrow Add Medication \rightarrow Click Clinical Reconciliation \rightarrow Select Patient \rightarrow Load HTML \rightarrow Merge both data \rightarrow Click ERX \rightarrow Click Prescribe \rightarrow View Merged Results.

E-Prescribing

EMR→E-Prescription→Search for the patient→Select Patient→Select Pharmacy→Add

allergies→Add Reactions→Click on Done with Allergies→Enter the medication to search→Click on

Find→Select medication→Check Drug interactions→Capture Sig→Select duration→Select

Quantity→Select Refills→Capture Directions to Pharmacist→Enter directions to patient→Click on

continue→Capture stop medication details→Click Ok→Sign the medication→Click on Send

§170.315(g)(3)—Safety-enhanced Design: System Usability Report

EHR Usability Test Report of Capella EHR V6.1

§170.315(b)(11) Decision support interventions

\$170.315(g)(3) –Safety-enhanced Design

Report based on Common Industry Format for Usability Test Reports

Date of Usability Test	11/30/2024
Date of Report	12/09/2024
Report Prepared By	Acurus Solutions
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UCD Process Applied

Name: NISTIR 7741

Description:

NIST guides those developing electronic health record (EHR) applications that need to know more about processes of user-centered design (UCD). An established UCD process ensures that designed EHRs are efficient, effective, and satisfying to the user. Following the guidance in this document will greatly increase the likelihood of achieving the goal of building usable user interfaces and a better user experience. One of the main purposes of this guide is to provide practical guidance on methods relating to UCD and usability testing.

NIST 7741 UCD processes was applied during the creation of the software for the below criteria to ensure the designed EHR is efficient, effective, and satisfying to the user

• §170.315(b)(11) Decision support interventions

Citation (URL and/or publication citation):

- Schumacher, R. and Lowry, S. (2010), (NISTIR 7741) NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records, NIST Interagency/Internal Report (NISTIR), National Institute of Standards and Technology, Gaithersburg, MD, [online], https://doi.org/10.6028/NIST.IR.7741, https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=907313 (Accessed December 19, 2024)
- https://www.nist.gov/publications/nistir-7741-nist-guide-processes-approach-improvingusability-electronic-health-records

Executive Summary

A usability test of Capella-EHR V6.1, a web based EHR system, was conducted on 11/30/2024 in the clinician's office in Pomona, CA. 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 matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

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

• Generating a predictive clinical note and providing feedback

During the 30 minute one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form. They were instructed that they could withdraw at any time. Participants had prior experience with the EHR.4 The administrator introduced the test and instructed participants to complete a series of tasks using the EHRUT. During the testing, the administrator timed the test and, along with the data logger(s) recorded user performance data on paper and electronically. The administrator did not give the participant assistance in how to complete the task.

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

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• 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. 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.

		Task Success	Path Deviation	Task Time	(in seconds)	Errors	Task Ratings (Likert Scale)
Task\Measure	#	Mean % (SD %)	Deviations (Observed /Optimal)	Mean (SD)	Deviations (Observed /Optimal)	Mean% (SD %)	Mean (SD)
Generate a predictive clinical note using Al and provide feedback	10	100(0)	12/9	186 (4.0)	193/180	3.50 (2.14)	4.50 (0.67)

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with these tasks to be: 92.6%. In addition to the performance data, the following qualitative observations were made:

Major Findings

1. Participant finds overall system is user friendly and easy to use.

Areas of Improvements

None

Introduction

The EHRUT tested for this study was the web-based application **Capella-EHR V6.1**. Designed to present medical information to the healthcare providers in an ambulatory setting across multiple specialties (Internal Medicine, Family Medicine etc..), the EHRUT consists of 1 tab meant to prepare the clinical notes. 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 Capella-EHR. To this end, measures of effectiveness, efficiency and user satisfaction, such as timing tasks, usability questionnaire, error reporting, and participant comments, were captured during the usability testing.

Method

Participants

A total of 10 participants were tested on the EHRUT. Participants in the test were a Medical Doctor, Nurse Practitioner and Physician Assistants. Participants were recruited by Acurus Solutions Inc. sales representatives and were compensated for their time. In addition, the participants had no direct connection to the development of or organization producing the EHRUT(s). Participants were not from the testing or supplier organization. Participants were given the opportunity to have the same orientation level of training as the actual end users would have received.

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Recruited participants had a mix of backgrounds and demographic characteristics. The following is a table of participants by characteristics, including demographics, professional experience, computing experience, and user needs for Assistive Technology (AT). Participant names were replaced with participant IDs so that an individual's data cannot be tied back to individual identities

Participant Identifier	Participant Gender	Participant Age	Participant Education	Participant Occupation /Role	Participant Professional Experience	Participant Computer Experience	Participant Product Experience	Participant Assistive Technology Needs
Participant 1	Female	60-69	Doctorate degree (e.g., MD, DNP, DMD, PhD)	MD	240	255	120	No
Participant 2	Male	40-49	Doctorate degree (e.g., MD, DNP, DMD, PhD)	MD	160	188	86	No
Participant 3	Male	60-69	Doctorate degree (e.g., MD, DNP, DMD, PhD)	MD	267	291	76	No
Participant 4	Female	50-59	Doctorate degree (e.g., MD, DNP, DMD, PhD)	MD	228	242	132	No
Participant 5	Male	70-79	Doctorate degree (e.g., MD, DNP, DMD, PhD)	RN	292	296	186	No
Participant 6	Female	40-49	Doctorate degree (e.g., MD, DNP, DMD, PhD)	MD	139	144	62	No
Participant 7	Male	40-49	Doctorate degree (e.g., MD, DNP, DMD, PhD)	MD	118	123	86	No
Participant 8	Female	70-79	Doctorate degree (e.g., MD, DNP, DMD, PhD)	MD	296	299	170	No
Participant 9	Male	60-69	Doctorate degree (e.g., MD, DNP, DMD, PhD)	MD	284	292	228	No
Participant 10	Male	60-69	Doctorate degree (e.g., MD, DNP, DMD, PhD)	MD	314	326	263	No

Ten (10) participants were recruited and all of them participated in the usability test. Zero participants failed to show for the study. Participants were tested individually and were scheduled for one session in which all modules were trained and tested.

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. During the usability test,

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participants interacted with Capella 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 analysed 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

Intended Users

Providers of practices in ambulatory setting across multiple specialties (Internal Medicine, Family Medicine etc..).

Tasks

To test the usability of 170.315(b)(11) Decision Support Interventions, following task is identified:

1. Generate a predictive clinical note using AI and provide feedback.

Procedures

Participants were instructed to perform the tasks as specific instructions below

- 1. As quickly as possible; however, accuracy is more important than speed on the tasks.
- 2. Without assistance; administrators were 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 participant indicated that they were ready. The task time was stopped once the participant indicated that they had successfully completed the task.

Following the session, the administrator gave each participant the post-test questionnaire and thanked everyone for their participation

Test Locations

The test location was on-site at the participants' medical practice/clinic where they work. Only the participant and administrator were in the test room. Because of the demand of work, the administrator set up a time for each participant as opposed to gathering all of them in one area all at the same time. Audio levels and distractions were kept to a minimum at an assigned room. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

Test Environment

The testing was conducted at a provider's facility in a designated room. For testing, the computers ran Windows 10 and above. The participants used the same computer, a mouse when using the EHR and were seated properly in a room where outside noise is controlled and kept to a minimum. The environment is setup with Display Monitor size of 19inch with screen resolution 1280 X 1024. The systems were connected to internet using High-Speed LAN. The application was set up by Acurus Solutions Inc. according to the vendor's documentation describing system set-up and preparation. The

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application was running on server setup using a test database. 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 magnification of the browser size)

Test Forms and Tools

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

- Task Steps
- Effectiveness measurement Table
- Efficiency Measurement Table
- Overall rating of the tasks
- System Usability Scale Questionnaire

Participant Instructions

The administrator reads 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 30 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

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

Data Scoring

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

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Measures	Rationale and Scoring
Effectiveness: Task	A task was counted as a "Success" if the participant was able to achieve the
Success	correct outcome, without assistance, within the time allotted on a per task basis.
	The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.
	Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency. Optimal task performance time, as bench-marked 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.
Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a "Failures." No task times were taken for errors.
	The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors. This should also be expressed as the mean number of failed tasks per participant.
Efficiency: Task Deviations	The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation. It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.
Efficiency: Task Time	Each task was timed from when the administrator said "Begin" until the participant said, "Done." If he or she failed to say "Done," the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.

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Measures	Rationale and Scoring
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate "Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. Common convention is that average ratings for systems judged easy to use should be 3.3 or above.
	To measure participants' confidence in and likeability of the Capella-EHR V5.4 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."

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 in below table. The results should be seen considering the objectives and goals outlined in Section Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance.

System Usability Test

Participant	System Usability Test Results
Participant 1	90.0%
Participant 2	100.0%
Participant 3	76.0%
Participant 4	92.0%
Participant 5	92.0%
Participant 6	100.0%
Participant 7	96.0%
Participant 8	88.0%
Participant 9	100.0%
Participant 10	92.0%

Discussion on the Findings

Effectiveness

Success was achieved in every outcome of this study; however, there was a little path deviation due to overlook.

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Efficiency

The participants were able to complete the task within the time as the system is intuitive and easy to use.

Satisfaction

Overall participants are satisfied with the technology as AI note feature is User Friendly

Major Findings

1. Participant finds overall system is user friendly and easy to use.

Areas of Improvements

None

Appendices

Effectiveness measurement Table

Task\Measure	Easily	Completed with	Not completed	Comments
	completed	difficulty or help		
Generate a predictive				
clinical note using AI				
and provide feedback				

Efficiency Measurement Table

Task\Measure	Time Taken	Comments
Generate a predictive clinical note		
using AI and provide feedback		

Overall rating of the tasks

Task\Measure	Very Difficult				Very Easy
Generate a predictive					
clinical note using AI and provide feedback	1	2	3	4	5

System Usability Scale Questionnaire

#	Question	Strongly disagree				Strongly agree
1	I think that I would like to use this					
	system frequently	1	2	3	4	5
2	I found the system unnecessarily					
	complex	1	2	3	4	5
3	I thought the system was easy to					
	use	1	2	3	4	5

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#	Question	Strongly disagree				Strongly agree
4	I think that I would need the					
	support of a technical person to be	1	2	3	4	5
	able to use this system					
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	1	2	3	4	5
	quickly					
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

Steps to complete the task

Generate a predictive clinical note using AI and provide feedback

- 1. Create Appointment and move the encounter to Provider Process
- 2. Open the Encounter as a Provider
- 3. Click on Akido Note
- 4. Choose the template as "Al Note"
- 5. Click on "Transcribe" to record and transcribe the conversation of the encounter
- 6. Once the transcription is done, click on Generate Summary for AI processing to predict the clinical note for the encounter
- 7. User reviews the clinical note and provides feedback in the form of corrections to the predicted clinical note.

Optimal Path to complete the task

My Q→Select Encounter→Click on Process Encounter→Click on Akido Note→Select AI Note→Click Transcribe to record clinical notes→Click Generate Summary to predict Clinical notes using AI→Review the clinical note→Provide feedback and corrections

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