ONC HIT Certification Program
Test Results Summary for 2014 Edition EHR Certification

Part 1: Product and Developer Information

1.1 Certified Product Information

Product Name:	Amrita Hospital Information System
Product Version:	6.1
Domain:	Inpatient
Test Type:	Complete EHR

1.2 Developer/Vendor Information

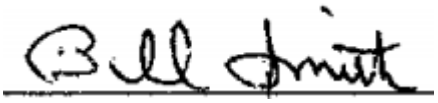
Developer/Vendor Name:	Amrita Ventures, LLC
Address:	10200 Crow Canyon Road Castro Valley CA 94552
Website:	www.amritamedical.com
Email:	Prasad@amritatech.com
Phone:	925-570-0744
Developer/Vendor Contact:	Keshav Prasad

Part 2: ONC-Authorized Certification Body Information

2.1 ONC-Authorized Certification Body Information

ONC-ACB Name:	Drummond Group
Address:	13359 North Hwy 183, Ste B-406-238, Austin, TX 78750
Website:	www.drummondgroup.com
Email:	ehr@drummondgroup.com
Phone:	817-294-7339
ONC-ACB Contact:	Bill Smith

This test results summary is approved for public release by the following ONC-Authorized Certification Body Representative:

Bill Smith	Certification Committee Chair
ONC-ACB Authorized Representative	**Function/Title**
 10/20/2014	
Signature and Date	

2.2 Gap Certification

The following identifies criterion or criteria certified via gap certification

§170.314			
[x] (a)(1)	[x] (a)(17)	[x] (d)(5)	[ ] (d)(9)
[x] (a)(6)	[x] (b)(5)*	[x] (d)(6)	[x] (f)(1)
[x] (a)(7)	[x] (d)(1)	[x] (d)(8)	

*Gap certification allowed for Inpatient setting only

[ ] No gap certification

2.3 Inherited Certification

The following identifies criterion or criteria certified via inherited certification

§170.314			
☐ (a)(1)	☐ (a)(14)	☐ (c)(3)	☐ (f)(1)
☐ (a)(2)	☐ (a)(15)	☐ (d)(1)	☐ (f)(2)
☐ (a)(3)	☐ (a)(16) *Inpt. only*	☐ (d)(2)	☐ (f)(3)
☐ (a)(4)	☐ (a)(17) *Inpt. only*	☐ (d)(3)	☐ (f)(4) *Inpt. only*
☐ (a)(5)	☐ (b)(1)	☐ (d)(4)	☐ (f)(5) *Optional & Amb. only*
☐ (a)(6)	☐ (b)(2)	☐ (d)(5)	
☐ (a)(7)	☐ (b)(3)	☐ (d)(6)	☐ (f)(6) *Optional & Amb. only*
☐ (a)(8)	☐ (b)(4)	☐ (d)(7)	
☐ (a)(9)	☐ (b)(5)	☐ (d)(8)	☐ (g)(1)
☐ (a)(10)	☐ (b)(6) *Inpt. only*	☐ (d)(9) *Optional*	☐ (g)(2)
☐ (a)(11)	☐ (b)(7)	☐ (e)(1)	☐ (g)(3)
☐ (a)(12)	☐ (c)(1)	☐ (e)(2) *Amb. only*	☐ (g)(4)
☐ (a)(13)	☐ (c)(2)	☐ (e)(3) *Amb. only*	

☒ No inherited certification

Part 3: NVLAP-Accredited Testing Laboratory Information

Report Number: GI-09292014-2853_A
Test Date(s): 09/29/2014; 09/28/2014

3.1 NVLAP-Accredited Testing Laboratory Information

ATL Name:	Drummond Group EHR Test Lab
Accreditation Number:	NVLAP Lab Code 200979-0
Address:	13359 North Hwy 183, Ste B-406-238, Austin, TX 78750
Website:	www.drummondgroup.com
Email:	ehr@drummondgroup.com
Phone:	512-335-5606
ATL Contact:	Beth Morrow

For more information on scope of accreditation, please reference NVLAP Lab Code 200979-0.

Part 3 of this test results summary is approved for public release by the following Accredited Testing Laboratory Representative:

Gary Isaac	Test Proctor
ATL Authorized Representative	**Function/Title**
GARY ISAAC 10/20/2014	Sarasota, FL
Signature and Date	**Location Where Test Conducted**

3.2 Test Information

3.2.1 Additional Software Relied Upon for Certification

Additional Software	Applicable Criteria	Functionality provided by Additional Software
ExitCare	170.314.a.15	InfoButton
MaxMD Direct mdEmail®	170.314.b.1, b.2	Direct messaging

Additional Software	Applicable Criteria	Functionality provided by Additional Software

☐ No additional software required

3.2.2 Test Tools

Test Tool	Version
☒ Cypress	2.4.1
☒ ePrescribing Validation Tool	1.0.4
☐ HL7 CDA Cancer Registry Reporting Validation Tool	1.0.3
☒ HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool	1.8
☒ HL7 v2 Immunization Information System (IIS) Reporting Validation Tool	1.8
☒ HL7 v2 Laboratory Results Interface (LRI) Validation Tool	1.7
☒ HL7 v2 Syndromic Surveillance Reporting Validation Tool	1.7
☒ Transport Testing Tool	179
☒ Direct Certificate Discovery Tool	3.0.2

☐ No test tools required

3.2.3 Test Data

☐ Alteration (customization) to the test data was necessary and is described in Appendix [*insert appendix letter*]

☒ No alteration (customization) to the test data was necessary

3.2.4 Standards

3.2.4.1 Multiple Standards Permitted

The following identifies the standard(s) that has been successfully tested where more than one standard is permitted

Criterion #	Standard Successfully Tested	
(a)(8)(ii)(A)(2)	☐ §170.204(b)(1) HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain	☐ §170.204(b)(2) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide

Criterion #	Standard Successfully Tested	
(a)(13)	[x] §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release	[x] §170.207(j) HL7 Version 3 Standard: Clinical Genomics; Pedigree
(a)(15)(i)	[x] §170.204(b)(1) HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain	[ ] §170.204(b)(2) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide
(a)(16)(ii)	[ ] §170.210(g) Network Time Protocol Version 3 (RFC 1305)	[x] §170. 210(g) Network Time Protocol Version 4 (RFC 5905)
(b)(2)(i)(A)	[ ] §170.207(i) The code set specified at 45 CFR 162.1002(c)(2) (ICD-10-CM) for the indicated conditions	[x] §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release
(b)(7)(i)	[ ] §170.207(i) The code set specified at 45 CFR 162.1002(c)(2) (ICD-10-CM) for the indicated conditions	[x] §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release
(e)(1)(i)	Annex A of the FIPS Publication 140-2 [*list encryption and hashing algorithms*] AES-256 SHA-256	
(e)(1)(ii)(A)(2)	[ ] §170.210(g) Network Time Protocol Version 3 (RFC 1305)	[x] §170. 210(g) Network Time Protocol Version 4 (RFC 5905)
(e)(3)(ii)	Annex A of the FIPS Publication 140-2 [*list encryption and hashing algorithms*]	
Common MU Data Set (15)	[x] §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release	[ ] §170.207(b)(2) The code set specified at 45 CFR 162.1002(a)(5) (HCPCS and CPT-4)

Criterion #	Standard Successfully Tested

☐ None of the criteria and corresponding standards listed above are applicable

3.2.4.2 Newer Versions of Standards

The following identifies the newer version of a minimum standard(s) that has been successfully tested

Newer Version	Applicable Criteria

☒ No newer version of a minimum standard was tested

3.2.5 Optional Functionality

Criterion #	Optional Functionality Successfully Tested
☐ (a)(4)(iii)	Plot and display growth charts
☐ (b)(1)(i)(B)	Receive summary care record using the standards specified at §170.202(a) and (b) (Direct and XDM Validation)
☐ (b)(1)(i)(C)	Receive summary care record using the standards specified at §170.202(b) and (c) (SOAP Protocols)
☐ (b)(2)(ii)(B)	Transmit health information to a Third Party using the standards specified at §170.202(a) and (b) (Direct and XDM Validation)
☐ (b)(2)(ii)(C)	Transmit health information to a Third Party using the standards specified at §170.202(b) and (c) (SOAP Protocols)
☐ (f)(3)	Ambulatory setting only – Create syndrome-based public health surveillance information for transmission using the standard specified at §170.205(d)(3) (urgent care visit scenario)
☐ Common MU Data Set (15)	Express Procedures according to the standard specified at §170.207(b)(3) (45 CFR162.1002(a)(4): Code on Dental Procedures and Nomenclature)
☐ Common MU Data Set (15)	Express Procedures according to the standard specified at §170.207(b)(4) (45 CFR162.1002(c)(3): ICD-10-PCS)

☒ No optional functionality tested

3.2.6 2014 Edition Certification Criteria* Successfully Tested

Criteria #	Version		Criteria #	Version	
	TP**	TD***		TP	TD
☐ (a)(1)	1.2	1.5	☒ (c)(3)	1.6	1.6
☒ (a)(2)	1.2		☐ (d)(1)	1.2	
☒ (a)(3)	1.2	1.4	☒ (d)(2)	1.5	
☒ (a)(4)	1.4	1.3	☒ (d)(3)	1.3	
☒ (a)(5)	1.4	1.3	☒ (d)(4)	1.3	
☐ (a)(6)	1.3	1.4	☐ (d)(5)	1.2	
☐ (a)(7)	1.3	1.3	☐ (d)(6)	1.2	
☒ (a)(8)	1.2		☒ (d)(7)	1.2	
☒ (a)(9)	1.3	1.3	☐ (d)(8)	1.2	
☒ (a)(10)	1.2	1.4	☐ (d)(9) *Optional*	1.2	
☒ (a)(11)	1.3		☒ (e)(1)	1.8	1.5
☒ (a)(12)	1.3		☐ (e)(2) *Amb. only*	1.2	1.6
☒ (a)(13)	1.2		☐ (e)(3) *Amb. only*	1.3	
☒ (a)(14)	1.2		☐ (f)(1)	1.2	1.2
☒ (a)(15)	1.5		☒ (f)(2)	1.3	1.7.1
☒ (a)(16) *Inpt. only*	1.3	1.2	☒ (f)(3)	1.3	1.7
☐ (a)(17) *Inpt. only*	1.2		☒ (f)(4) *Inpt. only*	1.3	1.7
☒ (b)(1)	1.7	1.4	☐ (f)(5) *Optional & Amb. only*	1.2	1.2
☒ (b)(2)	1.4	1.6			
☒ (b)(3)	1.4	1.2	☐ (f)(6) *Optional & Amb. only*	1.3	1.0.3
☒ (b)(4)	1.3	1.4			
☐ (b)(5)	1.4	1.7	☐ (g)(1)	1.7	1.9
☒ (b)(6) *Inpt. only*	1.3	1.7	☒ (g)(2)	1.7	1.9
☒ (b)(7)	1.4	1.6	☒ (g)(3)	1.3	
☒ (c)(1)	1.6	1.6	☒ (g)(4)	1.2	
☒ (c)(2)	1.6	1.6			

☐ No criteria tested

*For a list of the 2014 Edition Certification Criteria, please reference http://www.healthit.gov/certification (navigation: 2014 Edition Test Method)

**Indicates the version number for the Test Procedure (TP)

***Indicates the version number for the Test Data (TD)

3.2.7 2014 Clinical Quality Measures*

Type of Clinical Quality Measures Successfully Tested:

- [ ] Ambulatory
- [x] Inpatient
- [ ] No CQMs tested

*For a list of the 2014 Clinical Quality Measures, please reference http://www.cms.gov (navigation: 2014 Clinical Quality Measures)

Ambulatory CQMs							
CMS ID	Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
☐ 2		☐ 90		☐ 136		☐ 155	
☐ 22		☐ 117		☐ 137		☐ 156	
☐ 50		☐ 122		☐ 138		☐ 157	
☐ 52		☐ 123		☐ 139		☐ 158	
☐ 56		☐ 124		☐ 140		☐ 159	
☐ 61		☐ 125		☐ 141		☐ 160	
☐ 62		☐ 126		☐ 142		☐ 161	
☐ 64		☐ 127		☐ 143		☐ 163	
☐ 65		☐ 128		☐ 144		☐ 164	
☐ 66		☐ 129		☐ 145		☐ 165	
☐ 68		☐ 130		☐ 146		☐ 166	
☐ 69		☐ 131		☐ 147		☐ 167	
☐ 74		☐ 132		☐ 148		☐ 169	
☐ 75		☐ 133		☐ 149		☐ 177	
☐ 77		☐ 134		☐ 153		☐ 179	
☐ 82		☐ 135		☐ 154		☐ 182	

Inpatient CQMs							
CMS ID	Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
☒ 9	v2	☒ 71	v3	☒ 107	v2	☒ 172	v3
☒ 26	v1	☒ 72	v2	☒ 108	v2	☒ 178	v3
☒ 30	v3	☒ 73	v2	☒ 109	v2	☒ 185	v2
☒ 31	v2	☒ 91	v3	☒ 110	v2	☒ 188	v3
☒ 32	v3	☒ 100	v2	☒ 111	v2	☒ 190	v2
☒ 53	v2	☒ 102	v2	☒ 113	v2		
☒ 55	v2	☒ 104	v2	☒ 114	v2		
☒ 60	v2	☒ 105	v2	☒ 171	v3		

3.2.8 Automated Numerator Recording and Measure Calculation

3.2.8.1 Automated Numerator Recording

Automated Numerator Recording Successfully Tested			
☐ (a)(1)	☐ (a)(9)	☐ (a)(16)	☐ (b)(6)
☐ (a)(3)	☐ (a)(11)	☐ (a)(17)	☐ (e)(1)
☐ (a)(4)	☐ (a)(12)	☐ (b)(2)	☐ (e)(2)
☐ (a)(5)	☐ (a)(13)	☐ (b)(3)	☐ (e)(3)
☐ (a)(6)	☐ (a)(14)	☐ (b)(4)	
☐ (a)(7)	☐ (a)(15)	☐ (b)(5)	

☒ Automated Numerator Recording was not tested

3.2.8.2 Automated Measure Calculation

Automated Measure Calculation Successfully Tested			
☒ (a)(1)	☒ (a)(9)	☒ (a)(16)	☒ (b)(6)
☒ (a)(3)	☒ (a)(11)	☒ (a)(17)	☒ (e)(1)
☒ (a)(4)	☒ (a)(12)	☒ (b)(2)	☐ (e)(2)
☒ (a)(5)	☒ (a)(13)	☒ (b)(3)	☐ (e)(3)
☒ (a)(6)	☐ (a)(14)	☒ (b)(4)	
☒ (a)(7)	☒ (a)(15)	☐ (b)(5)	

☐ Automated Measure Calculation was not tested

3.2.9 Attestation

Attestation Forms (as applicable)	Appendix
☒ Safety-Enhanced Design*	A
☒ Quality Management System**	B
☒ Privacy and Security	C

*Required if any of the following were tested: (a)(1), (a)(2), (a)(6), (a)(7), (a)(8), (a)(16), (b)(3), (b)(4)

**Required for every EHR product

3.3 Appendices

Attached below.

Test Results Summary Change History

Test Report ID	Description of Change	Date
GI-09292014-2853	Added missing CQMs	20Oct2014

2014 Edition Test Report Summary

Amrita
Ventures, LLC.

Date: September 27, 2014

To whomever it may concern

We attest to the validity of the User Centric Design Report based on the study conducted on version 6.1 of Amrita Hospital Information System (AHIS 6.1).

Sincerely,

Ravikumar Nair

Amrita Ventures, LLC

EHR Usability Test Report of Amrita HIS 6.1

Amrita Ventures LLC

Amrita HIS 6.1

Inpatient Electronic Health Record

Usability Test Report

2014 Meaningful Use Edition

Data Services for Healthcare Foundation (DaSH)
503 North Main Street, Suite 654
Pueblo, CO 81003

Report based on NIST 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing

Dates of Usability Testing:	*8/1/2014 - 9/13/2014*
Date of Report:	*9/14/2014*
Report Prepared By:	*David Ginsberg, Interim Executive Director, DaSH* *PHONE: 719-225-8866* *Email: dginsberg@privaplan.com* *Address:* 503 North Main Street, Suite 654 Pueblo, CO 81003

Contents

1. EXECUTIVESUMMARY

Data Services for Healthcare Foundation is a 501(c) 3 not for profit organization developed to assist rural and community hospitals with various health information technology requirements. Among these is assistance with project management and implementation of a variety of inpatient CEHRT platforms. The organization was founded based upon a grant for rural health networks established in 2011 by the Health Services Resource Administration, an agency of the U.S. Department of Health and Human Services.

Since that time, we have conducted numerous inpatient CEHRT implementations and project coordination tasks requiring us to gain expertise in the usability of multiple platforms.

In this process we have interfaced with vendors for both design, support and remediation. Our focus has been the entire spectrum of implementation with a special emphasis on achieving the core and or menu set meaningful use objectives.

Additionally, DaSH was awarded a rural HIT workforce grant by HRSA to develop and deploy a curriculum graduating health information technology specialists who will be able to conduct implementation training and support for CEHRT. This program is one year into its three-year lifecycle and on track to graduate 45 specialists.

Combined these experiences provide DaSH with a unique perspective on UCD and the usability testing component that most testing organizations never gain.

A usability study was conducted on Amrita HIS 6.1 from August 1, 2014 to September 13, 2014, coordinated by the DASH group. The study was conducted with various users including Physicians, nurses (including nurse practitioners and physician assistants) and IT specialists/administrators

Testing was conducted either onsite or via Webex sessions with remote participants.

A total of 18 participants interacted with the application in this study. This included 9 Physicians, 4 nurses, 1 nurse practitioner and 4 IT Administrators. Some of the participants had experience with Amrita HIS previously, while other participants were using the system for the first time.

The primary purpose of this usability test was to prove that Amrita HIS 6.1 user interfaces can be used in a safe, efficient, and effective manner with regard to the eight prioritized certification criteria:

a. 170.314(a)(1) Computerized provider order entry
b. 170.314(a)(2) Drug-drug, drug-allergy interaction checks
c. 170 314(a)(6) Medication list
d. 170 314(a)(7) Medication allergy list

e. 170.314(a)(8) Clinical decision support (CDS)
f. 170.314(a)(16) Electronic medication administration record
g. 170.314(b)(3) Electronic prescribing
h. 170.314(b)(4) Clinical information reconciliation

The study collected data on tasks related to the following:

Computerized Provider Order Entry (314.a.1)

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

Drug-drug, drug-allergy interactions checks (314.a.2)

- Create drug-drug and drug-allergy interventions prior to CPOE completion
- Adjustment of severity level of drug-drug interventions (may be an admin type function)

Medication list (314.a.6)

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

Medication allergy list (314.a.7) – Inpatient

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

Clinical information reconciliation (314.b.4)

- Reconcile patient's active medication list with another source – Inpatient & Ambulatory • Reconcile patient's active problem list with another source
- Reconcile patient's active medication allergy list with another source

e-Prescribing (314.b.3)

- Prescribe non-controlled Rx
- Prescribe medication through Rx Report

The Usability test was conducted over a period of 60 to 90 minutes. The participants had been recruited and screened previously, and recruiting documents had been compiled separately. On the day of testing, each participant was given or emailed the relevant forms by the instructor, including the informed consent/release form (Appendix 1. Informed Consent Form); and each participant was instructed that he/she could withdraw at any time.

For the onsite participants, the moderator gave a briefing on the Usability testing procedure, made sure that the relevant forms were collected and provided an instruction sheet to participants to use to complete tasks. The moderator also spoke at the beginning and end of each task and asked participants to log or declare when they had finished each task. In addition, there was a timekeeper present in the onsite setting – his role was to record the time taken to complete each task (based on participant response saying the task was complete). The moderator did not give the participant assistance in completing the task unless the participant asked for help, or was not able to proceed after a significant period of time.

The following types of data were collected for each participant:

a. Percentage of tasks successfully completed within the allotted time without assistance (Pass)
b. Percentage of tasks successfully completed with one assist from the moderator (Pass with help)
c. Percentage of task failures (Fail)
d. Notes (Types of errors)
e. Participant's satisfaction rating of the system and detailed feedback on the system.

All participant data was de-identified. After the participant interaction with the system, they were asked to rate their experience with the system based on the System Usability Scale (SUS).

Participants were not compensated in monetary terms, however, certain donations were made in their name to their choice of charitable organizations.

Performance Data for participants tasks is compiled in table 1. Please note that not all participants were given all tasks – Clinical tasks were given to Physicians and Nursing professionals. Only Administrative tasks (configuration related) were given to Administrators and IT professionals.

Table# 1: Performance Summary

Clinical Participants	N (users)	Average Pass %	Average Pass with help %	Average Fail %	Average % Pass + Pass with help
Computerized Provider Order Entry	10	94.0	3.6	2.4	97.6
Drug-Drug and Drug-Allergy Interaction Warnings	10	97.2	1.8	0.9	99.1
Review medications and make updates based on the information provided.	10	100	0	0	100
Review allergies and make updates based on the information provided.	10	93.1	2.6	4.3	95.7
Review Alerts and Actions from Clinical Decision Support	5	92.0	3.0	5.0	95.0
Electronic Medication Administration Record	6	94.0	3.0	3.0	97.0
Send this Rx electronically	10	81.0	10.0	9.0	91.0
Reconcile specific clinical information based on the information provided	5	85.6	7.1	7.3	92.7

Overall 8 physicians, 6 nurses and 5 Administrators completed the study and responded to the System Usability Scale (SUS) feedback forms.
SUS Scores for the system were calculated at 67.64

QUALITATIVE FEEDBACK AND FINDINGS

In addition to calculating the SUS score, participants provided qualitative feedback toward the usability of the application. Also, the proctor was able to observe the interaction of the user with the application which is detailed in the findings.

Effectiveness
Overall users were able to complete most tasks on their own without any assistance. In the case of remote users, they were also able to follow the instruction sheet independently to complete tasks. Participants accessed favorites on the screen to order medication and Lab/radiology orders – in some cases, they used the autofill feature on the order screens. Users had some difficulty in performing tasks they had not done before such as eRx, and in some cases Clinical Decision Support workflows. Also, overriding Allergy interaction alerts took more time for certain users given the requirements to apply a coded reason for each override.

Efficiency

Participants that had prior experience to Amrita HIS or similar EMR systems were able to follow optimal paths to get to the task completion. Participants with no experience were initially slow in completing tasks, but became much faster in later steps as they were able to adapt to the navigability of the application.

Some participants verbalized the need for bigger fonts on some screens, especially screens with more data input requirements such as the medication ordering screen. Multiple screen alerts sometimes distracted users from the task.

IT Administrators were able to quite easily change configuration levels following optimal paths. Physicians and Nurses took more time and sometimes clicked to other screens when trying to complete non standard tasks such as Clinical Decision Support, or using assistive technology (i.e., the barcode reader). Even though Amrita HIS supports hot keys, hardly any of the users applied any short cut keys to navigate through the application – this could be seen as a training issue during system deployment.

Satisfaction:

SUS Scores for the application interaction based on responses from all participants came to 67.64. This is in line with most web applications across the industry. Overall participants expressed satisfaction with the features of the application, and verbalized that the interactions would be even easier once they had more familiarity with this system.

Major Findings

Participants with some level of familiarity or training with this EMR were able to perform tasks faster and navigate on optimal paths. However, almost all participants expressed appreciation about level of functionality in the system as well as the ease of use once they had gone through a few steps. In some cases, especially around allergy interaction screens, participants found multiple alerts distracting. While many participants did not use Clinical Decision support currently, they were able to see value in this feature. Some participants complained about the data set as they wanted to select different medications or different allergy interactions based on their experience.

Areas for Improvement

While participants generally expressed very positive feedback on the use of the system, there are certain areas of improvement. The use of bigger action buttons and fonts especially in complex screens might help certain participants in navigation. Reducing alerts, if possible, would lower the distraction level. This is in line with common findings related to alert fatigue. Also, allowing users to access features from multiple screens, without creating additional complexity and extra click throughs might also speed up interactions.

There is also a need to adequately train users based on their roles and communicate frequently about new users or better ways to access features. Feedback sessions at a periodic interval will provide inputs to development and continue to keep the application friendly to users.

2. INTRODUCTION

The Amrita HIS version 6.1 tested for this study is an end to end integrated system hospital information system/EHR which includes clinical as well as non-clinical modules targeted at efficient hospital administration. The application provides a user interface that can be configured for various roles including physicians, nurses, laboratory, outpatient service lines and administrators.

The purpose of this study was to test and validate the usability of the current user interface, and provide evidence of usability based on guidelines provided by NIIST. As such, the study evaluated system effectiveness, task efficiency, user satisfaction with the system. Another purpose was to get qualitative and quantitative feedback from various users in order to improve the system interactions.

3. UCD DESIGN PROCESS

The Amrita HIS user centered design process is aligned with the national Institute of standards and technology guidance specifically in the NISTIR 7741 and 7742 documentation.

The program for the user testing focused on the usability testing analysis and feedback components of the NIST UCD guidance. As the testing organization, we did not have a role in the actual development of the software and the internal user centered design efforts being conducted as part of that.

However our observation and discussions with Amrita HIS has demonstrated that the design process is based upon the classic Plan, Analyze, Test and Refine steps, including the process below:

- Planning and systems analysis working closely with the client by the implementation and systems analyst team
- Wire framework presentations and review of prototypes by the client
- Fine tuning and development
- Field testing deployment with the client
- Feedback and adjustments

4. STUDY METHOD

4.1. PARTICIPANTS

A total of 18 participants took part in this study. Clinical Participants in the test were individuals that work within an inpatient and outpatient healthcare environment. Other participants were IT Specialists and Administrators that tested the usability of the system from a configurability interactions standpoint. Participants were contacted by DASH to participate in the study. These participants were not involved in any way in the creation/development of the Amrita HIS and EHR. Participants were selected to be as close to actual users of the system in order to get a realistic test result.

The following is a table of participants by characteristics, including demographics, role, and product experience. Participant names were replaced with Participant IDs so that an individual's data cannot be tied back to individual identities. A summary of the participant demographics can be found in the Appendix.

Table # 2

PID	Job Role	Employment Location	Test Environment
N1	Nurse - ER	Hospital	In-Person
N2	Nurse - Anaesthesiology	Hospital	In-Person
N3	Advanced Nurse Practioner	Long term and Acute inpatient care	Remote
N4	Nurse - Inpatient	Hospital	Remote
N5	Nurse - Inpatient	Hospital/Critical Care	Remote
N6	Nurse – Inpatient	Hospital	Remote
P1	Physician - Hospitalist	Hospital	In-Person
P2	Physician - Oncology	Hospital	In-Person
P3	Physician – Internal Medicine	Hospital	Remote
P4	Physician - Internal Medicine	Hospital	Remote
P5	Physician - Pediatrics	Hospital	Remote
P6	Physician - Critical Care	Hospital	Remote
P7	Physician - ER	Hospital	Remote
P8	Physician – Pediatric Oncology	Hospital	Remote
A1	IT Specialist		In-Person
A2	Healthcare Network and Applications specialist		In-Person
A3	Consultant		Remote
A4	Department Administrator		Remote

Participants recruited for the test all participated in the study. The study was conducted both onsite at the test Lab as well as remotely over WebEx sessions.

Participants were advised that the test would take between 60 minutes to 75 minutes. Additional time was estimated for online meeting setup as well as for recording setups. Meetings lists were created and scheduled in calendars and invites and reminders were sent to participants atleast one day prior to their testing slot.

4.2. STUDY DESIGN

Overall, the objective of this test was to validate that Amrita HIS can be used in an effective and efficient manner per the prioritized certification parameters. In addition, the test objective was to identify any areas that were not easy for an average user to navigate through, so these could be optimized further.

The following types of data were collected for each participant:

a. Percentage of tasks successfully completed within the allotted time without assistance (Pass)
b. Percentage of tasks successfully completed with one assist from the moderator (Pass with help)
c. Percentage of task failures (Fail)
d. Notes (Types of errors)
e. Participant's satisfaction rating of the system and detailed feedback on the system.

All participant data was de-identified. After the participant interaction with the system, they were asked to rate their experience with the system based on the System Usability Scale (SUS).

Participants were not compensated in monetary terms; however, certain donations were made in their name to their choice of charitable organizations.

4.3. TASKS

A number of tasks were created for the users so they could test various scenarios in the system. These tasks were based on the high level criteria for this usability study.

- ✓ Login to the application with different user roles
- ✓ Selecting the patient record
- ✓ Placing new Medication Order
- ✓ Placing new Lab Order
- ✓ Over-ride allergy alert

- ✓ Placing new Radiology Order
- ✓ Review medication list
- ✓ Review lab orders
- ✓ Review radiology orders
- ✓ Change Medication order
- ✓ Over-ride allergy alert
- ✓ Change Lab order
- ✓ Change Radiology order
- ✓ Review Medication order list
- ✓ Review Lab order list
- ✓ Review Radiology order list
- ✓ Create drug-drug intervention prior to CPOE completion
- ✓ Adjustment of severity of drug-drug interventions
- ✓ Record Medication List (inpatient)
- ✓ Change Medication List (inpatient)
- ✓ Access Medication List (inpatient)
- ✓ Record Medication Allergy List
- ✓ Change Medication Allergy List
- ✓ Access Medication Allergy List
- ✓ Use Assistive Technology for EMR
- ✓ Reconcile Patient Active Medication List with another source (inpatient)
- ✓ Reconcile Patient Active Problem List with another source
- ✓ Reconcile Patient Active Medication Allergy List with another source
- ✓ Create new ePrescriptions
- ✓ Prescribe medication through Rx
- ✓ Review Clinical Decision Support rule Alerts and related information

4.4. PROCEDURE

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

All participants signed an informed consent form prior to the testing.

For the onsite participants, the moderator gave a briefing on the Usability testing procedure, made sure that the relevant forms were collected and provided an instruction sheet to participants to use to complete tasks.
In addition to the moderator, there was a timekeeper present – his role was to record the time taken to complete each task (based on participant response saying the task was complete).

Participants were instructed to perform the tasks:

- ✓ After listening to the instructions from the testing administrator.

- ✓ As quickly as possible making as few errors and deviations as possible

- ✓ Without assistance on the actual application

The moderator also spoke at the beginning and end of each task and asked participants to log or declare when they had finished each task. The moderator did not give the participant assistance in completing the task unless the participant asked for help, or was not able to proceed after a significant period of time.

Participants were given an instruction sheet for each task or group of tasks, which included details of patient ID numbers and drug names, allergy names, etc that were part the test data.

Participants were asked to indicate on the screen through a chat box whether they were successful in a particular task and also when it was completed. The application logged the timestamp of each task that was indicated complete by the participant.

For remote participants, sessions were conducted via Cisco Webex. Participants were informed that their sessions would be recorded including video of participant facial expressions, and were told to communicate via the chat application if they had technical questions. They were also asked to indicate when each task was done, after referring to the instruction sheet which had been emailed to them a day prior to their session. Initially the moderator activated the Webex session, tested all controls to make sure the session would run smoothly. Then access to the Amrita HIS application was given the participant and they were asked to proceed similar to the onsite sessions.

Following the session, the moderator administered the SUS and feedback form (Appendix). Remote participants were sent a link to a survey which included the same SUS questions as the onsite form.

Participant information, task performance, errors (number of errors and types), clickpath deviations, verbal responses, SUS responses, and task times were recorded.

4.5. TEST LOCATION

The onsite study was conducted in a conference room and studio facility. The participants were kept secluded from each other and their sessions were not held concurrently. The facility was sound proof, and included a black glass room to accommodate the time keeper. Participants were given a comfortable environment to sit in and interact with the system.

For the remote sessions, Cisco Webex was used as the collaboration tool. Sessions were scheduled individually with participants, and they were asked to check their internet connectivity and screen camera ahead of time. They were also asked to select a time and place where they would not be disturbed during this session. Control of the moderator's computer was passed to the participant and sessions were moderated using the same materials and methods as face-to-face sessions

4.6. STUDY TEST ENVIRONMENT

The test was done on PCs running Windows 7 or Linux. Users also used a mouse and keyboard while interacting with the EHR. Amrita HIS is a web based application; so all computers were connected on

the wired or wireless network.

Remote participants used their own laptop or PC and used any internet browser to access the Cisco Webex online meeting. Once connected, participants were given control of the moderators computer that was connected to Amrita HIS via the internet (through a secure connection).

4.7. STUDY TEST FORMS AND TOOLS

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

a) Informed consent
b) Moderator guide
c) Instruction Sheet
d) Post-test questionnaire – SUS form

Prior to the study session, recruiting forms were used to select and screen candidates. Documents are provided in the appendix.

4.8. STUDY PARTICIPANT INSTRUCTIONS

Dear Participant:

Great having you with us today. Welcome to this testing facility and thanks for participating in this study. We are going to start the session today – this session will last approximately 90 mins or so. As you may already know through your recruiting session, you are here to use and interact with the Hospital Information System version 6.1 developed by Amrita Medical Systems. This session is being used to see if the application can be certified toward Meaningful use 2.

I will provide you a list of steps to use the system and complete some tasks. 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.

The purpose of this study is not to test you - we are testing the system to see if something needs to be improved. So please don't worry if you are not able to complete any of the tasks. Do not do anything more than asked. Please save your detailed comments until the end of a task or the end of the session as a whole when we can discuss freely.

I will be here in case you have any specific questions, 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. If you feel it necessary, you can withdraw at any time during the testing.

So, once again the product being used today is Amrita HIS version 6.1. Obviously some of the data in the application is placeholder data, so please don't get confused with the accuracy of the date.

One final note - we are recording the audio and screenshots of our session today. The actual computer interaction will be recorded directly from the screen. There is a colleague of mine who will be timing how long it takes you to complete various tasks. So, as you are ready to start each task, please say aloud "Beginning Task". And when you believe you have completed the task, please say "End task". That way he will be able to accurately record the time for the completion of each task.

You will be testing on that computer there. This is also a Bar Code reader to use as assistive technology for medication administration. In one of the tasks, you will be asked to use this device based on the instructions.

All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time.

Once the tasks are done, I will ask you for your impressions and feedback.

Do you have any questions or concerns? Otherwise, we can get started with some basic questions and move on to testing the product.

For our study, let me ask you a few things:

- ✓ What is your job title / appointment?
- ✓ How long have you been working in this role?
- ✓ What are some of your main responsibilities?
- ✓ Tell me about your experience with electronic health records.

Ok, now we are ready to get started. Please refer to your instruction sheet, and follow the instructions.

4.9. 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, the goals of this test were to assess:

a) The efficiency of Amrita HIS by measuring the length of time it takes for a user to complete specific tasks; and the total number of tasks successfully completed during the study.

b) The efficiency of Amrita HIS by measuring the path deviations taken by the user during the tasks.
c) The effectiveness of Amrita HIS by measuring the number and types of errors experienced by the user during the tasks.
d) The satisfaction of the user with Amrita HIS by logging their comments on the tasks.

4.10 DATA SCORING

Data scoring details can be found below

Table #3

Measures	Rationale and Scoring
Task Success	A task was considered a success if the participant completed the task. To calculate the task success rate, the total number of successful tasks were divided by the total number of tasks completed. A task was counted as a "Pass with help" if the participant was able to achieve the correct outcome with minimal assist from the moderator. Both were combined to get the pass rate.
Task Errors	A task was considered a "Fail" if the participant abandoned the task or did not complete the task goal in the allotted time or became 'stuck' and could not proceed without asking for assistance. Error % for each task took the total number of errors for each task and divided that number by the total attempts at the task
Task Time	Timing started when the administrator said 'Begin'. The time ended when the participant indicated they had completed the task by typing the same in the chat application. The application automatically recorded the time stamp. Task times were only counted if the participant completed the task. The average time per task was calculated for each task.
Path Deviations Notes	Notes were taken when the participant's path (i.e., steps) through the application deviated from the optimal. 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. Notes were consolidated in major findings or efficiency.
Satisfaction - SUS Scores	At the end of the study a System Usability Scale questionnaire was sent to the participants. Responses were compiled and enumerated in the appendix.

5. DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. Participants who failed to follow session and task instructions had their data excluded from the analyses. The table provides a listing of all the usability steps performed and the performance of the study participants in each task and identifies the tasks performed and the performance level for each task.

The listing of the steps of each UCD Category are listed in following sections.

6. Scenario: 170.314 (a) (1) Computerized Order Entry

6.1. Participants

All scenarios were attempted by all participants including physicians, nurses as well as Administrators. A total of 18 participants completed this task. Only onsite participants completed the assistive technology scenario, using barcode scanners for medication and patient identifications and matching, as part of 170.314(a)(16) Electronic medication administration record.

170.314(a)(1) Computerized provider order entry
Enable a user to electronically record, change, and access the following order types i. Medications; ii. Laboratory; and iii. Radiology/imaging. Task: Order specific labs, diagnostic imaging, and medications from an orderset based on the information provided. Combined with: § 170.314(a)(2) Drug-drug, drug-allergy interaction checks - (i) Intervention § 170.314(a)(8) CDS (v) Source attributes

6.2. Task Listing and Instructions

To successfully complete the task, participants were required to do the steps below:

Table # 4: Computerized Provider Order Entry Criteria Mapped to Usability Test Tasks

Activty	Details
Login	mark >> %^$&#%

Selecting the patient record	IP list >> 314111				
Placing new Medication Order					
		digoxin 250 mcg oral tab	OD (noon)	0.25 mg tablet	Oral - no stop order
		iboprofen 800 mg oral tab	Q6H	800 mg tablet	Oral - no stop order
		temazepam 15 mg oral capsule	OD (Bedtime)	15 mg capsule	Oral - no stop order
Placing new Lab Order					
		Complete blood count (hemogram) panel in blood by automated count			
		Hemoglobin A1c/hemoglobin.total in blood			
		Gas & carbon monoxide panel in blood			
Over-ride allergy alert	Select EACH drug >> override reason >>				
Placing new Radiology Order					
		CT abdomen & pelvis w/ contrast material			
		Myocrd image PET perfus single study rest/stress			
Review medication list					
Review lab orders					
Review radiology orders					
Change Medication order					
		digoxin 250 mcg oral tab			
		digoxin 125 mcg oral tablet	OD (noon)	.125 mg tablet	Oral - no stop order

Over-ride allergy alert					
Change Lab order					
		Gas & carbon monoxide panel in blood			
		Gas and Carbon monoxide panel - Arterial blood			
Change Radiology order					
		CT abdomen & pelvis w/ contrast material			
		CT abdomen & pelvis w/o contrast material			
Review Medication order list					
Review Lab order list					
Review Radiology order list					
Logout					

6.3 Data Analysis and Reporting

Table 5: Usability Test Results for Each Subtask in the Computerized Provider Order Entry Task.

Measure	**N that Attempted Task**	**Task Success**				**Task Time (Sec)**	**Risk Rating (1-5); 1 is Riskiest**
Subtask	**#**	**% Pass + Pass with Help**	**% Pass**	**% Pass with Help**	**% Fail**	**Mean (SD)**	

Placing new Medication Order	10	100	100	0	0	22 (8)	2
Placing new Lab Order	10	100	94	6	0	18(6)	3
Over-ride allergy alert	10	94	88	6	6	20(4)	3
Placing new Radiology Order	10	100	94	6	0	18(6)	3
Review medication list	10	100	100	0	0	12 (3)	4
Review lab orders	10	100	100	0	0	13(4)	4
Review radiology orders	10	100	100	0	0	13(4)	4
Change Medication order	10	88	82	6	12	24 (6)	2
Change Lab order	10	94	88	6	6	18(6)	3
Change Radiology order	10	94	88	6	6	18(6)	3
Review Medication order list	10	100	100	0	0	11(2)	4
Review Lab order list	10	100	94	6	0	12(4)	4
Review Radiology order list	10	100	94	6	0	12(4)	4

6.4 Discussion of the Findings

The following sections describe the major findings in terms of Effectiveness, Efficiency, Areas of Improvement and Major Findings. Satisfaction was assessed at the system level, and is detailed in a later section along with the results of the System Usability Scale (SUS). The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

6.4.1 Effectiveness

Participants had different levels of errors or deviations mostly based on the level of experience with EHRs. Performance of subtasks was excellent in terms of placing new orders and medications, however, performance fell for changing orders and allergy alerts. Participants did use favorites or auto-complete when ordering new medications or lab and radiology orders.

6.4.2 Efficiency

Most users navigated through the optimal path to get to the end result. The use of different colors for action buttons seemed to make navigation easier for users. In some screens, the amount of data required users to spend more time through the steps such as medication order details. Also, the need to enter a reason for overriding an alert for drug-allergies or drug-drug CDS resulted in participants being slowed down. Some participants did not notice required fields, and had to go back before continuing to next screens.

6.4.3 Satisfaction

Satisfaction was evaluated at the system level. System Usability Scale (SUS) findings are detailed in a later section.

6.4.4 Major Findings

Performance of modifying orders and overriding allergy alerts was below the 95% success level. Some clinicians want to enter medication orders quickly with little scrolling or clicking – many experienced users were able to tab through various fields to complete tasks faster. Allergy alerts were distracting to some users, and they had some delay in navigating to override allergies.

6.4.5 Areas of Improvement

Overall, participants verbalized ease of use of the system, and were challenged to find ways to improve upon it. Those new to using the system were helpful to point out areas that are not as intuitive.

Highlighting fields or buttons with actionable colors might be helpful for users to easily identify next steps. Also, putting action buttons next to order or modify fields would make for quicker navigation. Font size could be made more flexible, especially for older users.

7. Scenario: 170.314(a)(2)Drug-drug, drug-allergy interaction checks

7.1. Participants

All scenarios were attempted by all participants including physicians, nurses as well as Administrators. A total of 18 participants completed this task. Only onsite participants completed the assistive technology scenario, using barcode scanners for medication and patient identifications and matching, as part of 170.314(a)(16) Electronic medication administration record.

§170.314 (a)(2) Drug-drug, drug-allergy interaction checks	
i.	Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.
ii.	Adjustments.
a.	Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.
b.	Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

.

7.2. Task Listing and Instructions

Table #6: To successfully complete the task, participants were required to do the steps below:

Activty	Details				
Login	mark >> %%^$^%				
Search and selecting the patient record	Ip list >> 314121				
Check the current allergies		enalapril			
Review the current medication orders					
		acyclovir 400 mg oral tablet, 400 mg, B.I.D			
		acarbose 100 mg oral tablet, 100 mg, O.D			
	Logout				
Login as user with admin privilege	masters >> ^&%**%^				
Adjust severity level to include all					
	Logout				
Login as user with CPOE privilege	mark >> %%^$^%				
Ordering of drug and review drug-drug interaction					
		tacrolimus 1 mg oral capsule	1 mg	BID	7 days
		warfarin 5 mg oral tablet	5 mg	OD	5 days
		enalapril 10 mg oral tablet	10 mg	BID	5 days
	Review Interaction alert >> cancel				
	Logout				
Login as user with admin privilege	masters >> ^&%**%^				
Adjust severity level for high					
	Logout				
Login as user with CPOE privilege	mark >> %%^$^%				
Order 2 drugs (for high and low drug-alert)					

		tacrolimus 1 mg oral capsule	1mg	BID	7 days
		warfarin 5 mg oral tablet	5 mg	OD	5 days
	Review the drug alert (only high)				
	cancel				
	Logout				
Login as user without admin privilege	betty >> ^&%^&%				
Check if severity level can be changed	no menu for the same				
	Logout				

7.3 Data Analysis and Reporting

Table# 7: Usability Test Results for Subtasks associated with Drug-Drug and Drug-Allergy Interaction Checks.

Measure	**N that Attempted Task**	**Task Success**				**Task Time (Sec)**	**Risk Rating (1-5); 1 is Riskiest**
Subtask	**#**	**% Pass + Pass with Help**	**% Pass**	**% Pass with Help**	**% Fail**	**Mean (SD) N Contributing to Mean**	
Search and selecting the patient record	10	100	100	0	0	8 (3)	5
Check the current allergies	10	100	100	0	0	16(6)	5
Review the current medication orders	10	100	100	0	0	18(4)	4
Login as user with admin privilege	10	100	100	0	0	4(2)	5
Adjust severity level to include all	10	94	88	6	6	32(6)	2
Login as user with CPOE privilege	10	100	100	0	0	4(2)	5
Ordering of drug and review drug-drug interaction	10	100	94	6	0	28(9)	2

Login as user with admin privilege	10	100	100	0	0	4(2)	5
Adjust severity level for high	10	94	88	6	6	14(6)	2
Login as user with CPOE privilege	10	100	100	0	0	4(2)	5
Order 2 drugs (for high and low drug-alert)	10	100	100	0	0	14(6)	2
Login as user without admin privilege	10	100	100	0	0	4(2)	5
Check if severity level can be changed	10	100	94	6	0	16(4)	3

7.4 Discussion of the Findings

The following sections describe the major findings in terms of Effectiveness, Efficiency, Areas of Improvement and Major Findings. Satisfaction was assessed at the system level, and is detailed in a later section along with the results of the System Usability Scale (SUS). The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

7.4.1 Effectiveness

Participants had different levels of errors or deviations mostly based on the level of experience with EHRs. Performance of subtasks was excellent in terms of logging in, placing and reviewing medications. In the case of changing interaction significance level, only one user had minor difficulty in navigation. Participants did use favorites or auto complete when ordering new medications or lab and radiology orders.

7.4.2 Efficiency

Most users navigated through the optimal path to get to the end result. The use of different colors for action buttons seemed to make navigation easier for users. In some screens, the amount of data required users to spend more time through the steps such as medication details. Also, the need to enter a reason for overriding an alert for drug-allergies or drug-drug CDS resulted in participants being slowed down.

7.4.3 Satisfaction

Satisfaction was evaluated at the system level. System Usability Scale (SUS) findings are detailed in a later section.

7.4.4 Major Findings

Performance related to drug-drug and drug-allergy interactions excellent and near or above the 95% confidence level. Modifying the interaction significance level saw two users getting stuck - resulting in it being below the 95% success level. One participant had a screen resolution issue via webex,

which was later resolved.

7.4.5 Areas of Improvement

Overall participants were able to complete their tasks quite effectively.

Highlighting fields or buttons with actionable colors might be helpful for users to easily identify next steps. Also, putting action buttons next to order or modify fields would make for quicker navigation. Font size could be made more flexible, especially for older users.

8. Scenario: 170 314(a)(6) Medication list

8.1. Participants

All scenarios were attempted by all participants including physicians, nurses as well as Administrators. A total of 18 participants completed this task. Only onsite participants completed the assistive technology scenario, using barcode scanners for medication and patient identifications and matching, as part of 170.314(a)(16) Electronic medication administration record.

§170.314 (a)(6) Medication List
Enable a user to electronically record, change, and access a patient's active medication list as well as medication history: i. Ambulatory setting. Over multiple encounters; or ii. Inpatient setting. For the duration of entire hospitalization

.

8.2. Task Listing and Instructions

Table #8: To successfully complete the task, participants were required to do the steps below:

Activty	Details				
Login	mark >> ^&%*				
Select the patient	IP list >> 314161				
Review the medication list					
		digoxin 250 mcg (0.25 mg) oral tablet, .25 mg, oral, O.D(Noon)			
		ibuprofen 800 mg oral tablet, 800 mg, oral, Q8H			

		temazepam 15 mg oral capsule, 15 mg, oral, O.D (Bedtime)			
		fluticasone CFC free 220 mcg/inh inhalation aerosol, oral, B.I.D			
Order new medications					
	no-stop order	buPROPion 150 mg/24 hours (XL) oral tablet, extended release			
		esomeprazole 40 mg oral delayed release capsule			
Review the medication list					
Change the medication order					
	discontinue	digoxin 250 mcg (0.25 mg) oral tablet			
		ibuprofen 800 mg oral tablet			
		temazepam 15 mg oral capsule			
	New	ibuprofen 800 mg oral tablet	Q6h: No stop order	800 mg tablet	Oral
		temazepam 30 mg oral capsule	OD: No stop order	30 mg tablet	Oral
Review the medication list	For active medication orders				
Review medication history	For other orders not active				
	Logout				

8.3 Data Analysis and Reporting

Table #9: Usability Test Results for Each Subtask in the Medication List Task

Measure	N that Attempted Task	Task Success	Task Time (Sec)	Risk Rating (1-5); 1 is Riskiest

Subtask	#	% Pass + Pass with Help	% Pass	% Pass with Help	% Fail	Mean (SD) N Contributing to Mean	
Review the medication list	10	100	100	0	0	12 (4)	4
Order new medications	10	100	100	0	0	18 (3)	2
Review the medication list	10	100	100	0	0	8 (3)	4
Change the medication order	10	100	100	0	0	20 (4)	2
Review the medication list	10	100	100	0	0	8 (3)	4
Review medication history	10	100	100	0	0	6 (2)	4

8.4 Discussion of the Findings

The following sections describe the major findings in terms of Effectiveness, Efficiency, Areas of Improvement and Major Findings. Satisfaction was assessed at the system level, and is detailed in a later section along with the results of the System Usability Scale (SUS). The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

8.4.1 Effectiveness

Participants were able to do all tasks at 100% effectiveness.

8.4.2 Efficiency

Most users navigated through the optimal path to get to the end result. The use of different colors for action buttons seemed to make navigation easier for users. In some screens, the amount of data required users to spend more time through the steps such as medication details. Also, the need to place in a reason for overriding an alert for drug-allergies or drug-drug CDS resulted in participants being slowed down.

8.4.3 Satisfaction

Satisfaction was evaluated at the system level. System Usability Scale (SUS) findings are detailed in a later section.

8.4.4 Major Findings

Medication ordering was achieved with 100% success. Some participants did take more time than others, especially with regards to the details around medication dosage and schedule, but were able

to complete tasks effectively.

8.4.5 Areas of Improvement

Overall participants were able to complete their tasks quite effectively.

Highlighting fields or buttons with actionable colors might be helpful for users to easily identify next steps. Also, putting action buttons next to order or modify fields would make for quicker navigation. Font size could be made more flexible, especially for older users.

9. Scenario: 170.314(a)(7) Medication allergy list

9.1. Participants

All scenarios were attempted by all participants including physicians, nurses as well as Administrators. A total of 18 participants completed this task. Only onsite participants completed the assistive technology scenario, using barcode scanners for medication and patient identifications and matching, as part of 170.314(a)(16) Electronic medication administration record.

170 314(a)(7) Medication allergy list
Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history: ii. Inpatient setting. For the duration of entire hospitalization

9.2. Task Listing and Instructions

Table #10: To successfully complete the task, participants were required to do the steps below:

Activity	Details			
Login	mark >> $%$##			
Select the patient	IP list >> 314171			
Review the current drug allergies				
Enter new drug allergies		drug	ibuprofen	reaction
Review the new list of drug allergies				
Make changes to the drug allergies				
	inactive		insulin	
	replace		cefaclor	with >> cefadroxil
			ibuprofen	with >> celecoxib

Review the revised list of drug allergies				
Check the medication allergy history				
	Logout			

9.3 Data Analysis and Reporting

Table #11: Usability Test results for Each Subtask in the Medication Allergy Task

Measure	**N that Attempted Task**	**Task Success**				**Task Time (Sec)**	**Risk Rating (1-5); 1 is Riskiest**
Subtask	**#**	**% Pass + Pass with Help**	**% Pass**	**% Pass with Help**	**% Fail**	**Mean (SD) N Contributing to Mean**	
Select the patient	10	100	100	0	0	8 (2)	5
Review the current drug allergies	10	100	100	0	0	8 (2)	4
Enter new drug allergies	10	88	82	6	12	32 (4)	2
Review the new list of drug allergies	10	100	100	0	0	8 (2)	4
Make changes to the drug allergies	10	88	82	6	12	36 (4)	2
Review the revised list of drug allergies	10	100	100	0	0	8 (2)	4
Check the medication allergy history	10	94	88	6	6	8 (2)	4

9.4 Discussion of the Findings

The following sections describe the major findings in terms of Effectiveness, Efficiency, Areas of Improvement and Major Findings. Satisfaction was assessed at the system level, and is detailed in a later section along with the results of the System Usability Scale (SUS). The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

9.4.1 Effectiveness

Most users were able to complete the task. The application provides a coversheet with a listing of medication and allergy details upon selecting the patient, so some of the steps were extremely

effective and efficient. Some users had difficult entering the reaction levels and severity levels for allergies. There were many optional fields, but some users did complete all of them as well.

9.4.2 Efficiency

Most users navigated through the optimal path to get to the end result. However, some participants slowed down on the actual allergy entry screens. Some users could not find the correct allergic reaction to the drugs ordered – this is more of a dataset issue versus an application problem.

9.4.3 Satisfaction

Satisfaction was evaluated at the system level. System Usability Scale (SUS) findings are detailed in a later section.

9.4.4 Major Findings

Performance related to entering new medication and allergies was good, though two steps were below the 94% success level. Mostly participants were somewhat confused by the dataset in not finding the correct allergy interaction. Also, some participants spent more time filling out optional fields in the interaction screens.

9.4.5 Areas of Improvement

Overall participants were able to complete their tasks quite effectively.

Highlighting fields or buttons with actionable colors might be helpful for users to easily identify next steps. Also, putting action buttons next to order or modify fields would make for quicker navigation. Font size could be made more flexible, especially for older users.

10. Scenario: 170.314(a)(8) Clinical decision support (CDS)

10.1. Participants

All scenarios were attempted by all participants including physicians, nurses as well as Administrators. A total of 18 participants completed this task. Only onsite participants completed the assistive technology scenario, using barcode scanners for medication and patient identifications and matching, as part of 170.314(a)(16) Electronic medication administration record.

170 314(a)(8) Clinical Decision Support
Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data: (A) Problem list;

(B) Medication list; (C) Medication allergy list; (D) Demographics; (E) Laboratory tests and values/results; and (F) Vital signs.

10.2. Task Listing and Instructions

Table #12: To successfully complete the task, participants were required to do the steps below:

Activity	Details
Login	mark >> $%$##
Select the patient	IP list >> 314181
Enter the Dx	Acute Ischemic Stroke - 433.11 or 433.10 ICD CDS alert is shown with the Reference link Click on link to open up UPTODATE with relevant information
Enter the Drug	amiodarone - Drug Pregnancy warning CDS alert is shown with the Reference link open UPTODATE with relevant information
For Asian Demographic Patient	Enter ICD 435.9 CDS alert is shown with the Reference link open up UPTODATE with relevant information
Enter Allergy	penicillin CDS alert is shown with the Reference link open UPTODATE with relevant information Logout

10.3: Data Analysis and Reporting

Table #13: Usability Test results for Each Subtask in the CDS Task

Measure	N that Attempted Task	Task Success				Task Time (Sec)	Risk Rating (1-5); 1 is Riskiest
Subtask	#	% Pass + Pass with Help	% Pass	% Pass with Help	% Fail	Mean (SD) N Contributing to Mean	

Select the patient	5	100	100	0	0	8 (2)	5
Enter the Dx	5	100	100	0	0	26 (4)	3
Enter new drug	5	88	82	6	12	32 (4)	2
Enter new Allergy	5	94	88	6	6	28 (4)	2
Select Patient Demographics as "Asian"	5	94	88	6	6	14(4)	3
Review the CDS Alerts	5	94	94	0	6	8 (2)	4

10.4 Discussion of the Findings

The following sections describe the major findings in terms of Effectiveness, Efficiency, Areas of Improvement and Major Findings. Satisfaction was assessed at the system level, and is detailed in a later section along with the results of the System Usability Scale (SUS). The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

10.4.1 Effectiveness

Most users were able to complete the task and were able to get the Alert based on criteria provided. Performance did not fall below the 94% level. The application provides a coversheet with a listing of medication, diagnosis and allergy details upon selecting the patient, so some of the steps were extremely effective and efficient.

10.4.2 Efficiency

Most users navigated through the optimal path to get to the end result. One participant could not find the CDS alert – this was later identified as a pop-up blocker issue in that user's computer. However, some participants slowed down on the actual allergy entry screens.

10.4.3 Satisfaction

Satisfaction was evaluated at the system level. System Usability Scale (SUS) findings are detailed in a later section.

10.4.4 Major Findings

Performance related to CDC alerts was above the 94% level. Most participants were comfortable with getting CDC alerts based on provided criteria.

10.4.5 Areas of Improvement

Overall participants were able to complete their tasks quite effectively.

Highlighting fields or buttons with actionable colors might be helpful for users to easily identify next steps. Also, putting action buttons next to order or modify fields would make for quicker navigation. Font size could be made more flexible, especially for older users.

11. Scenario: 170.314(a)(16) Electronic medication administration record

11.1. Participants

All scenarios were attempted by all participants including physicians, nurses as well as Administrators. A total of 18 participants completed this task. Only onsite participants completed the assistive technology scenario, using barcode scanners for medication and patient identifications and matching, as part of 170.314(a)(16) Electronic medication administration record.

	170 314(a)(16) Inpatient setting only - electronic medication administration record
§ 170.314(a)(16) Inpatient setting only - electronic medication administration record	
i.	In combination with an assistive technology that provides automated information on the "rights" specified in paragraphs (a)(16)(i)(A) through (E) of this section, enable a user to electronically verify the following before administering medication(s):
a.	Right patient. The patient to whom the medication is to be administered matches the medication to be administered.
b.	Right medication. The medication to be administered matches the medication ordered for the patient.
c.	Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient.
d.	Right route. The route of medication delivery matches the route specified in the medication order.
e.	Right time. The time that the medication was ordered to be administered compared to the current time.

11.2. Task Listing and Instructions

Table #14: To successfully complete the task, participants were required to do the steps below:

Activity	Details
Choose a time server from ITS list	
Synchronize the time	
Verify the time diff is within 5 sec	
Show the display of time in EHR as per system time	

Login	mark >>&^%^&\				
Select patient 1	3141161				
order medication					
		Ativan 2 mg oral tablet	Q8H	2 mg tablet	Oral
		warfarin 3 mg oral tablet (O.D)	OD	3 mg tablet	Oral
Select patient 2	3141162				
order medication					
		ampicillin 500 mg oral capsule	OD	500 mg capsule	Oral
	Logout				
Login as user with eMAR privilege	ruth >>&%^%$				
select patient	3141161				
Review the eMAR list					
Administer using assistive technology	scan	mrd 3141161	Drug NDC: 64455006501		
Check if bar code is able to identify patient, drug, dose, route, time	5R checked				
Administer using assistive technology	scan	mrd 3141161	Drug NDC: 68382005410		
Check if bar code is able to identify patient, drug, dose, route, time	5R checked				
Select patient 2	3141162				
Review the eMAR list					
Incorrect patient scan shows "wrong patient"	scan	mrd 3141161	Drug NDC: 64455006501		
Incorrect drug scan shows "wrong medication"	scan	mrd 3141162	Drug NDC: 64455006501		
Incorrect dose results in "wrong dose"	scan	mrd 3141162	Drug NDC: 68115003240		
Incorrect route results in "wrong route"	scan	mrd 3141162	Drug NDC: 66860001502		
Incorrect time results in "wrong time"	scan	mrd 3141162	Drug NDC: 68115003340		
	Logout				

11.3 Data Analysis and Reporting

Table #15: Usability Test Results for Each Subtask in the Electronic Administration Record Task.

Measure	N that Attempted Task	Task Success				Task Time (Sec)	Risk Rating (1-5); 1 is Riskiest
Subtask	#	% Pass + Pass with Help	% Pass	% Pass with Help	% Fail	Mean (SD) N Contributing to Mean	
Select patient 1	6	100	100	0	0	8 (2)	5
order medication	6	100	100	0	0	28 (3)	2
Select patient 2	6	100	100	0	0	8 (2)	5
order medication	6	100	100	0	0	28 (3)	2
Login as user with eMAR privilege	6	100	100	0	0	4 (2)	5
select patient	6	100	100	0	0	8 (2)	5
Review the eMAR list	6	100	100	0	0	8 (2)	4
Administer using assistive technology	6	88	76	12	12	24 (5)	1
Check if bar code is able to identify patient, drug, dose, route, time	6	100	100	0	0	8 (2)	3
Administer using assistive technology	6	94	88	6	6	24 (5)	1
Check if bar code is able to identify patient, drug, dose, route, time	6	94	88	6	6	8 (2)	3
Select patient 2	6	100	100	0	0	8 (2)	5
Review the eMAR list	6	100	100	0	0	8 (2)	4
Incorrect patient scan shows "wrong patient"	6	94	88	6	6	8 (2)	3
Incorrect drug scan shows "wrong medication"	6	94	88	6	6	8 (2)	3
Incorrect dose results in "wrong dose"	6	94	88	6	6	8 (2)	3
Incorrect route results in "wrong route"	6	94	88	6	6	8 (2)	3

Incorrect time results in "wrong time"	6	94	88	6	6	9	(2)	3

11.4 Discussion of the Findings

The following sections describe the major findings in terms of Effectiveness, Efficiency, Areas of Improvement and Major Findings. Satisfaction was assessed at the system level, and is detailed in a later section along with the results of the System Usability Scale (SUS). The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

11.4.1 Effectiveness

Most users were able to complete the task – performance level was a 100% success.

11.4.2 Efficiency

Most users navigated through the optimal path to get to the end result. However, some participants slowed down on the first attempt with the barcode scanner. Users that had used such equipment before were quite comfortable with the device integration.

Satisfaction

Satisfaction was evaluated at the system level. System Usability Scale (SUS) findings are detailed in a later section.

11.4.3 Major Findings

The assistive technology was tested using a barcode scanner to identify medications, patient and the match between the two. This task could only be completed by onsite participants. Most users had some delay in the beginning scan, but improved dramatically thereafter.

11.4.4 Areas of Improvement

Overall participants were able to complete their tasks quite effectively.

Ability to create screen capture of barcodes could help dramatically. Highlighting fields or buttons with actionable colors might be helpful for users to easily identify next steps. Also, putting action buttons next to order or modify fields would make for quicker navigation. Font size could be made more flexible, especially for older users.

12. Scenario: 170.314(b)(3) Electronic prescribing

12.1. Participants

All scenarios were attempted by all participants including physicians, nurses as well as Administrators. A total of 18 participants completed this task. Only onsite participants completed the assistive technology scenario, using barcode scanners for medication and patient identifications and matching, as part of 170.314(a)(16) Electronic medication administration record.

	170 314(b)(13) Electronic Prescribing. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:
i.	The standard specified in §170.205(b)(2); and
ii.	At a minimum, the version of the standard specified in § 170.207(d)(2).

12.2. Task Listing and Instructions

Table #16: To successfully complete the task, participants were required to do the steps below:

Activity	**Details**				
Login	erxone >> %^%^%				
Select the patient record	3142301				
Create SCRIPT newRX prescriptions					
		hydrochlorothiazide 50 mg oral tablet	50 mg tablet	30 days	favorites
	Dish Rx	eRx	refill (1)		
	medication order	send-to-ext-ph	Test One ph		
	logout				

12.3: Data Analysis and Reporting

Table 16: Usability Test Results Associated with the ePrescribe Task

Measure	**N that Attempted Task**	**Task Success**				**Task Time (Sec)**	**Risk Rating (1-5); 1 is Riskiest**
Subtask	**#**	**% Pass + Pass with Help**	**% Pass**	**% Pass with Help**	**% Fail**	**Mean (SD) N Contributing to Mean**	

Select the patient record	10	100	100	0	0	8 (2)	5
Create SCRIPT new RX prescriptions	10	94	82	12	6	34 (4)	1

12.4: Discussion of the Findings

The following sections describe the major findings in terms of Effectiveness, Efficiency, Areas of Improvement and Major Findings. Satisfaction was assessed at the system level, and is detailed in a later section along with the results of the System Usability Scale (SUS). The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

12 .4.1 Effectiveness

Most users were able to complete the task. Performance did fall below 94% when users were not able to generate an eprescription and could not continue on the remaining steps.

12.4.2 Efficiency

Most users navigated through the optimal path to get to the end result. However, some participants check boxes. Also, users had some navigation difficulty in trying to select a new pharmacy versus having it already preset for them.

12.4.3 Satisfaction

Satisfaction was evaluated at the system level. System Usability Scale (SUS) findings are detailed in a later section.

12.4.4 Major Findings

Performance was not as good as some of the other criteria, mostly driven by user difficulty on the medication screen to find the eRx check box. This could be addressed via training – this was also influenced because functionality might not have been used by the majority of testers in this study. For example, most hospital-based nurses do not use E-prescribing as part of their job.

12.4.5 Areas of Improvement

Overall participants were able to complete their tasks quite effectively.

Highlighting fields or buttons with actionable colors might be helpful for users to easily identify next steps. Also, putting action buttons next to order or modify fields would make for quicker navigation. Font size could be made more flexible, especially for older users. More prominent displays of the eRX check box would definitely help.

13. Scenario: 170.314(b)(4) Clinical information reconciliation

13.1. Participants

All scenarios were attempted by all participants including physicians, nurses as well as Administrators. A total of 18 participants completed this task. Only onsite participants completed the assistive technology scenario, using barcode scanners for medication and patient identifications and matching, as part of 170.314(a)(16) Electronic medication administration record.

	170 314(b)(13) (b)(4) Clinical information reconciliation (CDS)
i.	Enable a user to electronically reconcile the data that represent a patient's active
ii.	Medication, problem, and medication allergy list as follows. For each list type: Electronically and simultaneously display (i.e., in a single view) the data from at least two list 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.

13.2. Task Listing and Instructions

Table #17: To successfully complete the task, participants were required to do the steps below:

Activity	Details			
Login	mark >> %^%*%			
Select the patient				
Open patient EMR		MRD 314241		
Prepare 2 medication list with 1 identical drug		Reconciliation	Admission	
Review both the medication list				
Merge the list into a single reconciled list	Merge	Consolidated list (only unique)		
Review the final list to ensure drug is not duplicated				
Remove one of the medication from the consolidated list	Select metoprolol	discontinue		reconcile
Review the final medication list				
Select the patient record		314241		
Prepare 2 problem list with 1 identical problem		Reconciliation		
Review both the problem list				
Merge the list into a single reconciled list	Merge	Consolidated list (only unique)		

Review the final list to ensure problem is not duplicated				
Remove one of the problem from the consolidated list	Atrial fibrillation	remove	reconcile	
Review the final problem list				
Select the patient record				
Prepare 2 allergy list with 1 identical allergy	reconciliation			
Review both the allergy list				
Merge the list into a single reconciled list	Merge			
Review the final list to ensure allergy is not duplicated	Allergy			
Remove one of the allergy from the consolidated list				
Review the final allergy list				
Logout				

13.3 Data Analysis and Reporting

Table #18: Usability Test Results for Subtasks Associated with the Clinical Reconciliation Task

Measure	**N that Attempted Task**	**Task Success**				**Task Time (Sec)**	**Risk Rating (1-5); 1 is Riskiest**
Subtask	**#**	**% Pass + Pass with Help**	**% Pass**	**% Pass with Help**	**% Fail**	**Mean (SD) N Contributing to Mean**	
Browse and View CCDA	5	100	100	0	0	10(2)	2
Prepare 2 medication list with 1 identical drug	5	100	94	6	0	36 (6)	2
Merge the list into a single reconciled list	5	82	70	12	18	45 (9)	1
Prepare 2 problem list with 1 identical problem	5	100	94	6	0	36 (6)	2
Merge the list into a single reconciled list	5	82	70	12	18	45 (9)	1

13.4 Discussion of the Findings

The following sections describe the major findings in terms of Effectiveness, Efficiency, Areas of Improvement and Major Findings. Satisfaction was assessed at the system level, and is detailed in a later section along with the results of the System Usability Scale (SUS). The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

13.4.1 Effectiveness

82% of users could complete this task. Users that completed the first set of tasks were able to complete the tasks with the other parameters since these were mostly repetitive.

13.4.2 Efficiency

Most users navigated through the optimal path to get to the end result.

13.4.3 Satisfaction

Satisfaction was evaluated at the system level. System Usability Scale (SUS) findings are detailed in a later section.

13.4.4 Major Findings

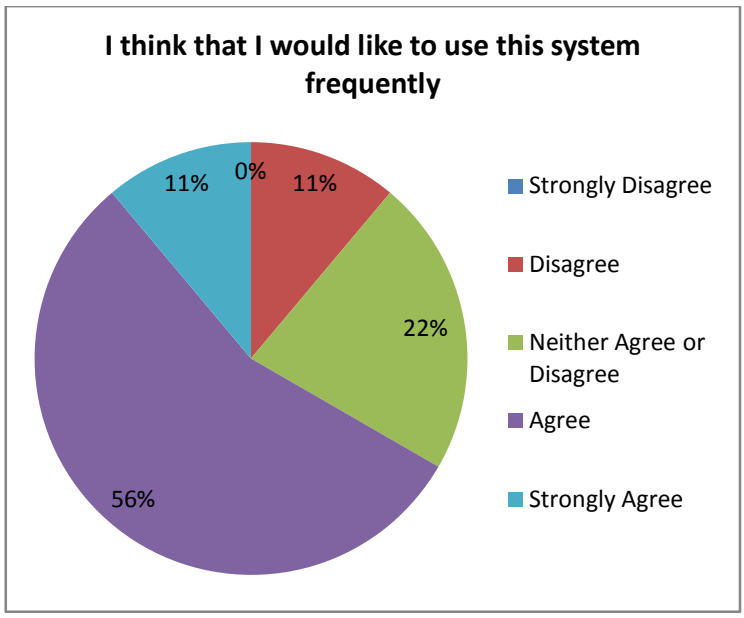
None of the participants had any experience or training with this feature. Performance completing reconciliation was below 95%. Mostly participants were somewhat confused by the steps and the dataset in the first criteria – once they were able to complete the first criteria, they were able to finish the remaining ones. Overall, more training on this feature will be needed for more effective completion.

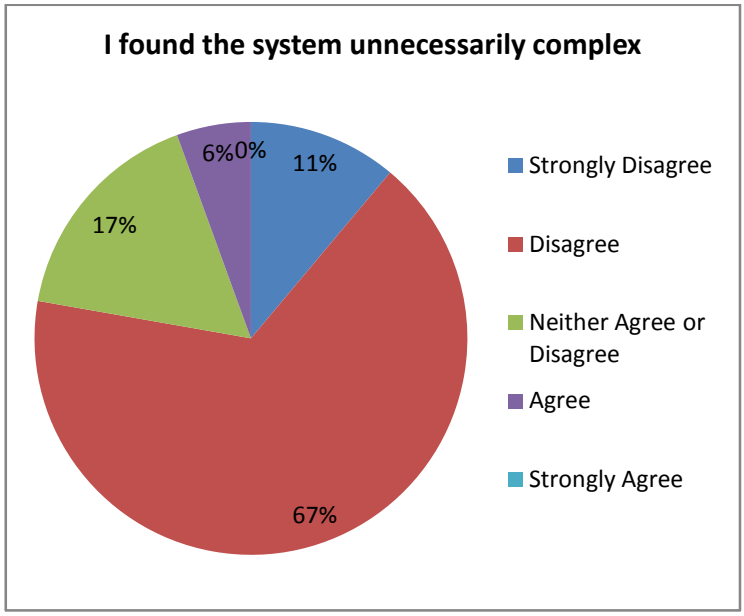
13.4.5 Areas of Improvement

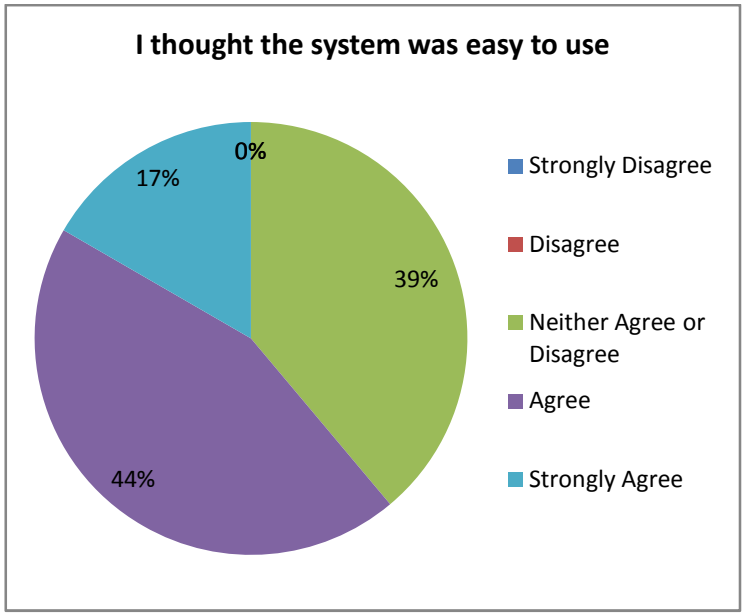
More training on this feature will dramatically improve completion. Highlighting fields or buttons with actionable colors might be helpful for users to easily identify next steps. Also, putting action buttons next to order or modify fields would make for quicker navigation. Font size could be made more flexible, especially for older users.

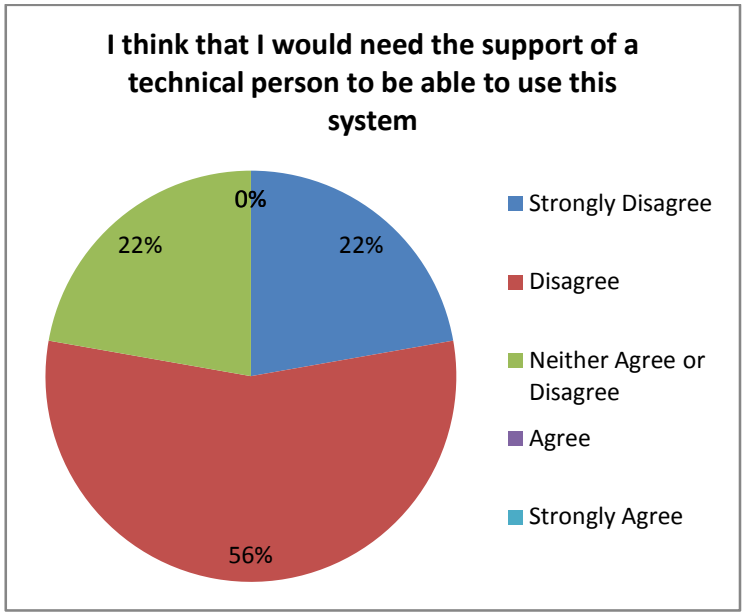
14. System Usability Scale (SUS)

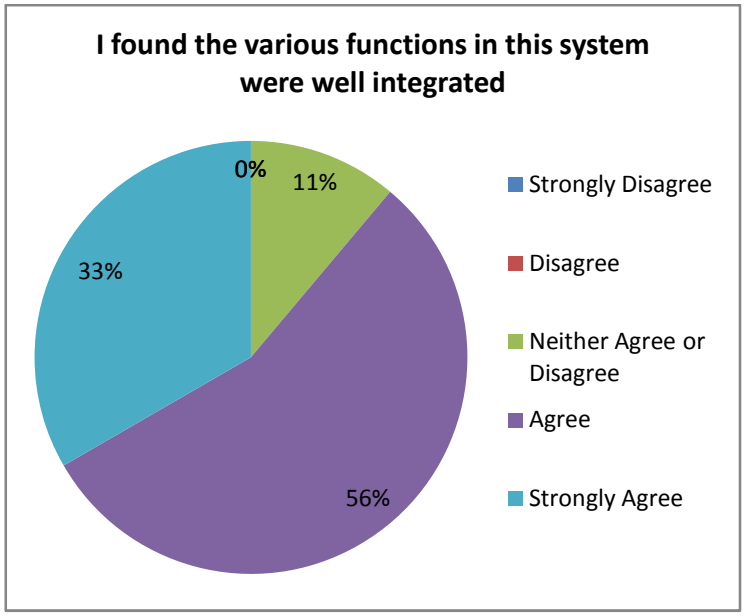
Eight physicians, 6 nurses and 4 administrators completed the SUS questionnaire at the end oftheir session. In addition, feedback was also obtained regarding system usability and areas of improvement. SUS was conducted via an anonymous online survey. Responses were compiled and graphically plotted.

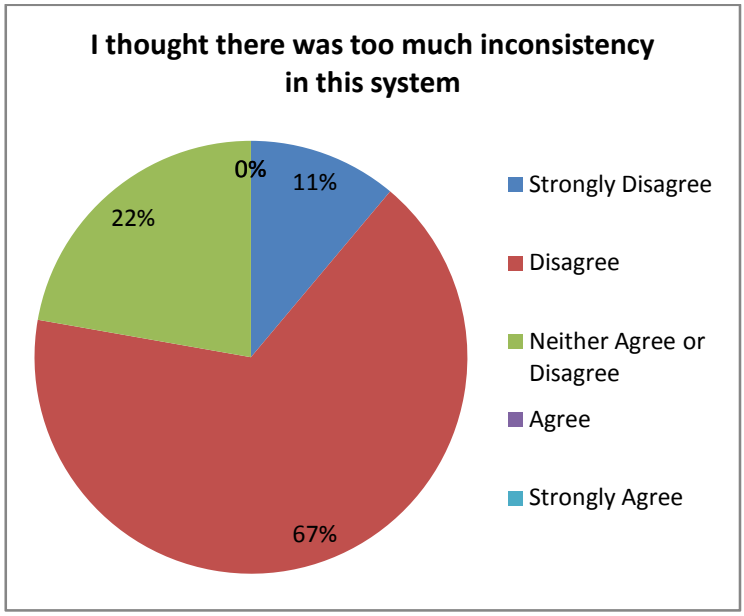

I think that I would like to use this system frequently
0%
11%
11%
22%
56%
Strongly Disagree
Disagree
Neither Agree or Disagree
Agree
Strongly Agree

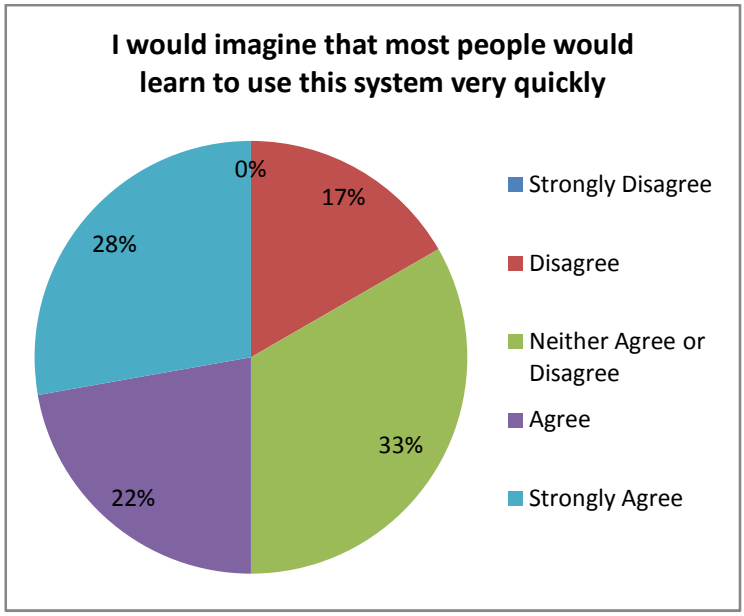

I found the system unnecessarily complex
6%
0%
11%
17%
67%
Strongly Disagree
Disagree
Neither Agree or Disagree
Agree
Strongly Agree

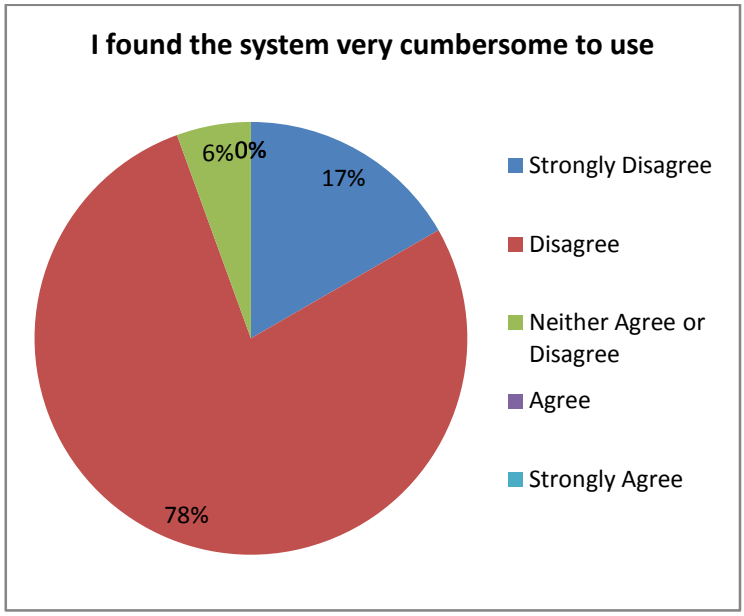

I thought the system was easy to use
0%
17%
39%
44%
Strongly Disagree
Disagree
Neither Agree or Disagree
Agree
Strongly Agree

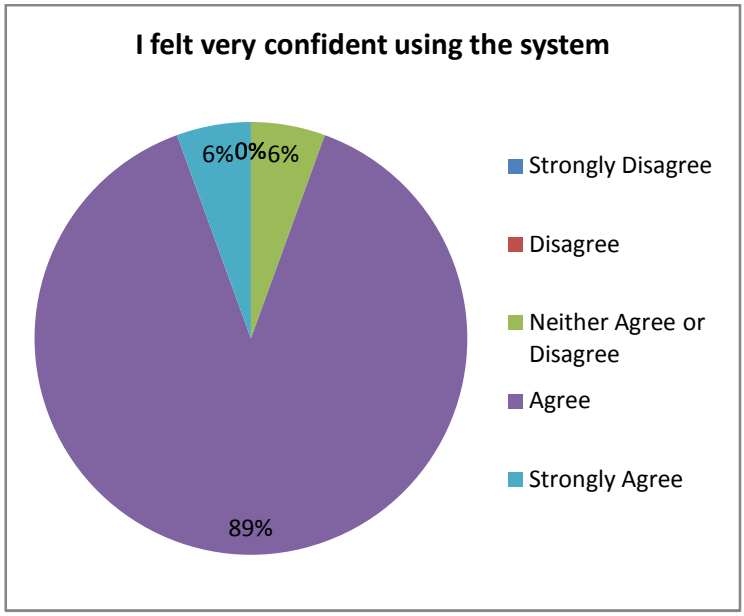

I think that I would need the support of a technical person to be able to use this system
0%
22%
22%
56%
Strongly Disagree
Disagree
Neither Agree or Disagree
Agree
Strongly Agree

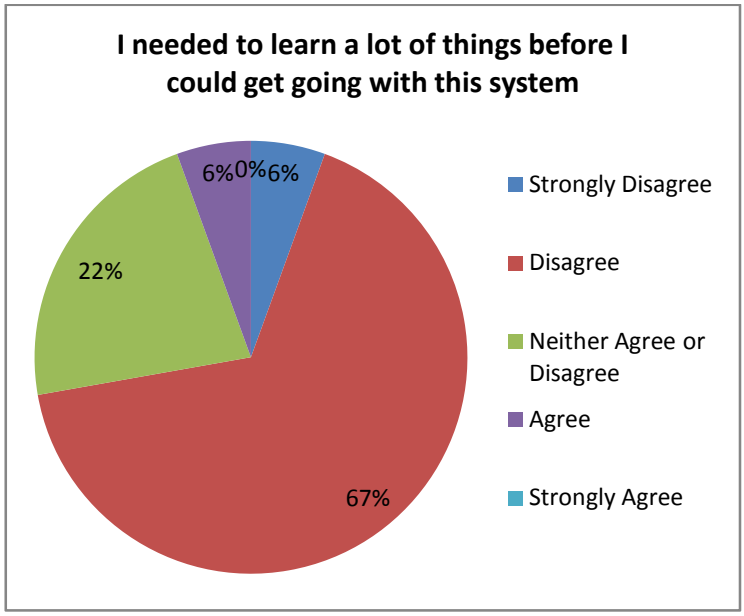

I found the various functions in this system were well integrated
0%
11%
33%
56%
Strongly Disagree
Disagree
Neither Agree or Disagree
Agree
Strongly Agree


I thought there was too much inconsistency in this system
0%
11%
22%
67%
Strongly Disagree
Disagree
Neither Agree or Disagree
Agree
Strongly Agree


I would imagine that most people would learn to use this system very quickly
0%
17%
28%
33%
22%
Strongly Disagree
Disagree
Neither Agree or Disagree
Agree
Strongly Agree


I found the system very cumbersome to use
6%
0%
17%
78%
Strongly Disagree
Disagree
Neither Agree or Disagree
Agree
Strongly Agree


I felt very confident using the system
6%
0%
6%
89%
Strongly Disagree
Disagree
Neither Agree or Disagree
Agree
Strongly Agree


I needed to learn a lot of things before I could get going with this system
6%
0%
6%
22%
67%
Strongly Disagree
Disagree
Neither Agree or Disagree
Agree
Strongly Agree

15. Appendix

MODERATOR INTRODUCTORY SESSION

Dear Participant:

Great having you with us today. Welcome to this testing facility and thanks for participating in this study. We are going to start the session today – this session will last approximately 90 mins or so. As you may already know through your recruiting session, you are here to use and interact with the Hospital Information System version 6.1 developed by Amrita Medical Systems. This session is being used to see if the application can be certified toward Meaningful use 2.

I will provide you a list of steps to use the system and complete some tasks. 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.

The purpose of this study is not to test you - we are testing the system to see if something needs to be improved. So please don't worry if you are not able to complete any of the tasks. Do not do anything more than asked. Please save your detailed comments until the end of a task or the end of the session as a whole when we can discuss freely.

I will be here in case you have any specific questions, 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. If you feel it necessary, you can withdraw at any time during the testing.

So, once again the product being used today is Amrita HIS version 6.1. Obviously some of the data in the application is placeholder data, so please don't get confused with the accuracy of the date.
One final note - we are recording the audio and screenshots of our session today. The actual computer interaction will be recorded directly from the screen. There is a colleague of mine who will be timing how long it takes you to complete various tasks. So, as you are ready to start each task, please say aloud "Beginning Task". And when you believe you have completed the task, please say "End task". That way he will be able to accurately record the time for the completion of each task.

You will be testing on that computer there. This is also a Bar Code reader to use as assistive technology for medication administration. In one of the tasks, you will be asked to use this device based on the instructions.

All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time.

Once the tasks are done, I will ask you for your impressions and feedback.
Do you have any questions or concerns? Otherwise, we can get started with some basic questions and move on to testing the product.

For our study, let me ask you a few things:

What is your job title / appointment? How long have you been working in this role? What are some of your main responsibilities? Tell me about your experience with electronic health records.

Data Services for Healthcare ("DaSH") User Centered Design Evaluation

Informed Consent

DaSH would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health records system. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about90minutes, depending on the particular areas you were asked to evaluate. In some cases the study will require less time.

Agreement

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

I understand and consent to the use and release of the web meeting facial recording by *DaSH*. I understand that the information and recording is for research purposes only and that my name and image will not be used for any purpose other than research. I relinquish any rights to the recording and understand the recording will only be copied internally for analysis purposes. Otherwise it shall not be disclosed except for requirements by the certification body authorized by the Office of the national coordinator underneath the Department of Health and Human Services. Such disclosure Will purely be for the purpose of evidence that testing did occur.

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

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

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

Please check one of the following:

YES, I have read the above statement and agree to be a participant. □□NO, I choose not to participate in this study.

Signature: _____

Date: _____

Non-Disclosure Agreement

THIS AGREEMENT is entered into as of _ _____ _, *2014*, between _____ ("the Participant") and the testing organization, Data Services for Healthcare Foundation ("DaSH").

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

By way of illustration, but not limitation, Confidential Information includes System user Interface and screens, and the underlying functionality.

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

Participant's printed name: _____

Signature: _____ Date: _____

Please scan and fax/e-mail or send by mail to the following address.

Mark See

VP Operations & CIO

Data Services for Healthcare (DaSH)

503 N. Main Street, Suite 123

Pueblo, CO 81003

(F): 719-225-8867

Email: msee@dashnetwork.org

Recruiting Script used during recruitment

Hello, my name is _____. We are recruiting individuals to participate in a usability study for an electronic health record. We would like to ask you a few questions to see if you qualify and if would like to participate. This should only take a few minutes of your time. This is strictly for research purposes. If you are interested and qualify for the study, you will be paid to participate. Can I ask you a few questions?

1. Are you male or female? [only ask this question if not obvious]

2. Have you participated in a focus group or usability test in the past *12* months? [If yes, Terminate]

3. Do you, or does anyone in your home, work in marketing research, usability research,? [If yes, Terminate]

4. Do you, or does anyone in your home, have a commercial or research interest in an electronic health record software or consulting company? [If yes, Terminate]

5. Which of the following best describes your age? [23 to 39; 40 to 59; 60 - to 74; 75 and older] [Recruit Mix]

6. Which of the following best describes your race or ethnic group? [e.g., Caucasian, Asian, Black/African-American, Latino/a or Hispanic, etc.]

7. Do you require any assistive technologies to use a computer? [if so, please describe]

Professional Demographics

8. What is your current position and title? (Must be healthcare provider)

RN: Specialty _____

Physician: Specialty _____

Administrative Staff

9. How long have you held this position?

10. Describe your work location (or affiliation) and environment? (Recruit according to the intended users of the application)

11. Which of the following describes your highest level of education? [e.g., high school

graduate/GED, some college, college graduate (RN, BSN), postgraduate (MD/PhD), other (explain)]

Computer Expertise

12. Besides reading email, what professional activities do you do on the computer? [e.g., access EHR, research; reading news; shopping/banking; digital pictures; programming/word processing, etc.]

13. About how many hours per week do you spend on the computer?

14. What computer platform do you usually use? [e.g., Mac, Windows, etc.]

15. What Internet browser(s) do you usually use? [e.g., Firefox, IE, Chrome, etc.]

16. In the last month, how often have you used an electronic health record?

17. How many years have you used an electronic health record?

18. How many EHRs do you use or are you familiar with?

19. How does your current or past work environment use patient records?

    On paper Some paper, some electronic All electronic

Contact Information

Those are all the questions I have . Your background matches the people we're looking.

Would you be able to participate on [date, time]? [If so collect contact information]

May I get your contact information?

Name of participant:

Address: City, State, Zip:

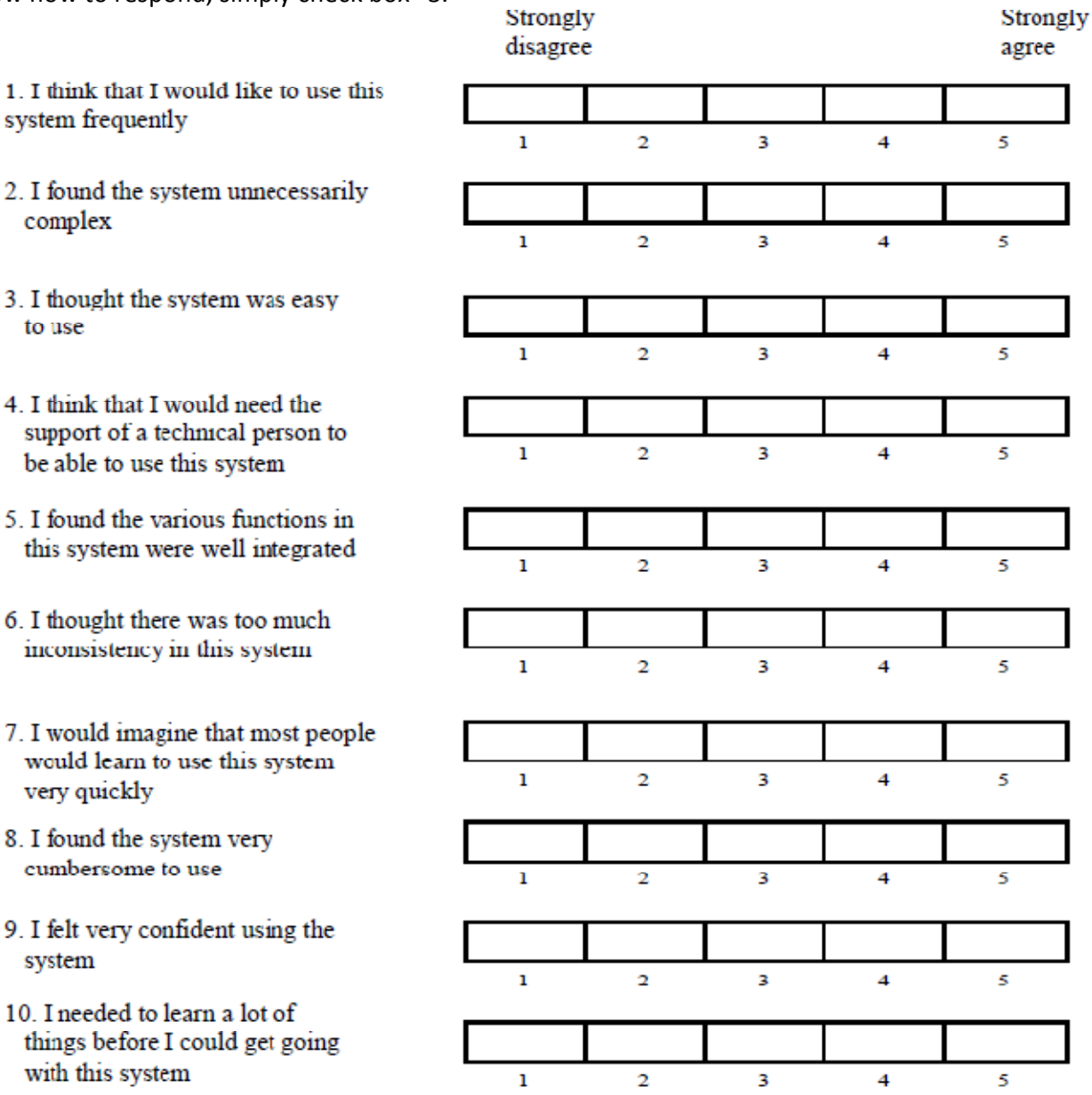
Daytime phone number: Evening phone number:

Alternate [cell] phone number: Email address:

Before your session starts, we will ask you to sign a release form allowing us to record your session. The record will only be used internally for further study if needed. Will you consent to be videotaped?

Appendix6: System Usability Scale Questionnaire

Considering your experience with the EHR in the session today, mark the box that reflects your immediate response to each statement. Make sure you respond to every statement. If you don't know how to respond, simply check box "3."



Amrita Ventures, LLC.

September 15, 2014

Drummond Group, Inc.
13359 North Hwy 183
Ste. B-406-238
Austin, TX 78750

To whom it may concern:

Amrita Ventures is currently adopting a homegrown Quality management System based on Agile development methodology and SDLC. Though, not all components of ISO-9001 are incorporated at this time into our homegrown QMS, Our overall strategy is to obtain ISO-9001 certification followed by CMMI.

Amrita Ventures applied this “home-grown” QMS for development, testing, implementation, and maintenance of all criteria measures in the 2014 edition of Meaningful Use.

Depending on the size, timeframe, complexity, experience profile of the team assigned to and user styles, Amrita Ventures adopts an intelligent blend of SDLC and/or Agile methodologies in development, implementation and maintenance of each project.

Besides user requirements from specific clients, market trends, growth in the industry, technology advancement, compliance standards, certification needs, all together drive the product roadmap. Product architects and key stakeholders meet periodically to evaluate the business value and criticality of each item from the product roadmap and commit to a product release appropriately.

System requirements Study (SRS), Solution mapping and Gap analysis, Detailed Design, Test plan documents are created, reviewed and signed-off for acceptance by clients as needed. While the core development (DEV) teams focus on the product roadmap items, the professional services (PS) team works with the onsite implementation teams in addressing the customization needs.

In addition to informal peer-reviews, there are mandatory formal code reviews in every release cycle. These reviews are conducted by technical managers and team leads, where all the code generated or modified in the current release cycle is inspected line by line. There are biweekly releases from development sprints to help achieve a quicker, efficient, and stable integration of independently developed but cross-functional code within the overall Development team.

There are also automated nightly builds primarily for the benefit of the developers who can see in about a short daily cycle whether or not their changes accidentally broke any existing product feature instead of waiting for days to learn the same. Towards the end of the release cycle, the development team enters into a ‘code-freeze’ phase for the Release team to build a version of the product for the QA team.

If QA discovers any bugs at this point, the developers fix those bugs and the Release team makes a new release available to QA. This process is repeated till QA can flag the build as completely bug-free. Once QA has flagged the build as being bug-free and meeting the requirements set out in the beginning of the release cycle, the Release team generates the CD ISO image of the release.

As projects mature and stabilize a formal transition is conducted where the project artifacts, charter of open issues, client contacts and other pertinent information are transferred via a series of Knowledge transfer meetings from the DEV and PS teams to the Customer support (CS) team.

Both internal and client reported defects are logged in appropriate defect tracking tools and based on the severity, client priority and service level agreements (SLA) maintenance releases are issued. Each team within Amrita Ventures has well-established escalation channels, which is made transparent to the clients for overall effectiveness.

In all the above functions, every step of the way, quality is maintained, measured and wherever possible improved by applying the QMS processes throughout.

Sincerely,

Ravikumar Nair
Member of Board

Amrita Ventures, LLC.

Ravikumar Nair
Member of Board
r.nair@amritamedical.com
925-570-0744

September 8, 2014

Dear Test Proctor,

1. **Are default settings for audit log and audit log status record are enabled by default?**
   Yes. Briefly describe how the EHR SUT enables the default settings.
   [IN170.314(d)(2)-1.01-1.02]

   In Amrita HIS, audit Log is enabled by default. The default settings can be seen in the Application Administration area by privileged users only.
   In Amrita HIS, the audit log status is always enabled and cannot be disabled.

2. **Is encryption of electronic health information on end-user devices is enabled by default?**
   Yes. Briefly describe how the EHR SUT enables the default settings.

   OR

   No. Explain how the EHR SUT does not store electronic health information on end-user devices.
   [IN170.314(d)(2)-1.03]

   Amrita HIS is a browser based application and does not store Electronic health information on end-user devices. “No-cache” headers are used to prevent the end-user device caching.

3. **Does the EHR SUT allow a user to disable the following?**
   - audit log
   - audit log status
   - encryption status

   [IN170.314(d)(2)-2.02 / IN170.314(d)(2)-2.09]

   - In Amrita HIS, audit Log can be disabled/enabled. It is a restrictive feature and can be performed by privileged users (administrator) only.
   - Audit Log status cannot be disabled.

- Encryption status is not applicable as no electronic health information is stored on the end-user devices.

4. **Does the EHR SUT permit any users to delete electronic health information?**
   [IN170.314(d)(2)-3.04]

   Amrita HIS does not allow any user to delete the electronic health information. It is only possible to inactivate a record, which is no longer presented to the user on the screen or is presented in an inactive status.

5. **Describe how the audit logs are protected from being changed, overwritten or deleted by the EHR technology**.
   [IN170.314(d)(2)-4.01]

   In Amrita HIS, audit log entries are always Insert events and no Update or Delete options are available. Audit logs are accessible only to the Application Administrator, who can view the audit logs as reports.

6. **Describe how the EHR is capable of detecting whether the audit logs have been altered.**
   [IN170.314(d)(2)-5.01]

   Every audit event generated by Amrita HIS is stored with a SHA-1 hash. Since this hash is generated based on the content of the audit log record, any alterations in the audit log record content would make the hash invalid and thus provides a way to detect alterations.

Sincerely,

Ravikumar Nair
Member of Board