Part 2: ONC-Authorized Certification Body Information

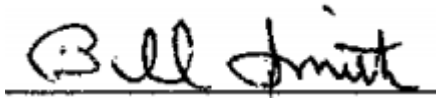
2.1 ONC-Authorized Certification Body Information

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
ONC-ACB Authorized Representative

Certification Committee Chair
Function/Title


4/2/2014
Signature and Date

2.2 Gap Certification

The following identifies criterion or criteria certified via gap certification

§170.314			
☐ (a)(1)	☐ (a)(17)	☒ (d)(5)	☐ (d)(9)
☐ (a)(6)	☐ (b)(5)*	☒ (d)(6)	☐ (f)(1)
☐ (a)(7)	☒ (d)(1)	☒ (d)(8)	

*Gap certification allowed for Inpatient setting only

☐ No gap certification

2.4 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: AMB-04012014-1904

Test Date(s): 03122014, 03142014, 04012014

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:	512-633-9510
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:

Alex Burt	Test Proctor
ATL Authorized Representative	**Function/Title**
 4/2/2014	Remote Observation, Nashville TN
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
DoseSpot	(a)1, (a)2, (a)6, (a)7,	CPOE, eRx
ExitCare	(a)15	Patient Education
DataMotion Direct	(b)1, (b)2, (e)1	Direct Messaging
Spreadsheet Software	(a)14	Patient lists

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	1.0.3
☐ HL7 CDA Cancer Registry Reporting Validation Tool	1.0.3
☐ HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool	1.7
☒ HL7 v2 Immunization Information System (IIS) Reporting Validation Tool	1.7.1
☒ HL7 v2 Laboratory Results Interface (LRI) Validation Tool	1.7
☒ HL7 v2 Syndromic Surveillance Reporting Validation Tool	1.7
☒ Transport Testing Tool	177
☒ Direct Certificate Discovery Tool	2.1

☐ 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	[ ] §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)	[ ] §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*] SSL 128 bit SHA1	
(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*] SSL 128 bit SHA1	
Common MU Data Set (15)	[ ] §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release	[x] §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
[x] (a)(1)	1.2	1.5	[x] (c)(3)	1.6	1.6
[x] (a)(2)	1.2		[ ] (d)(1)	1.2	
[x] (a)(3)	1.2	1.4	[x] (d)(2)	1.4	
[x] (a)(4)	1.4	1.3	[x] (d)(3)	1.3	
[x] (a)(5)	1.4	1.3	[x] (d)(4)	1.2	
[x] (a)(6)	1.3	1.4	[ ] (d)(5)	1.2	
[x] (a)(7)	1.3	1.3	[ ] (d)(6)	1.2	
[x] (a)(8)	1.2		[x] (d)(7)	1.2	
[x] (a)(9)	1.3	1.3	[ ] (d)(8)	1.2	
[x] (a)(10)	1.2	1.4	[ ] (d)(9) *Optional*	1.2	
[x] (a)(11)	1.3		[x] (e)(1)	1.7	1.4
[x] (a)(12)	1.3		[x] (e)(2) *Amb. only*	1.2	1.5
[x] (a)(13)	1.2		[x] (e)(3) *Amb. only*	1.3	
[x] (a)(14)	1.2		[x] (f)(1)	1.2	1.2
[x] (a)(15)	1.5		[x] (f)(2)	1.3	1.7.1
[ ] (a)(16) *Inpt. only*	1.3	1.2	[x] (f)(3)	1.3	1.7
[ ] (a)(17) *Inpt. only*	1.2		[ ] (f)(4) *Inpt. only*	1.3	1.7
[x] (b)(1)	1.6	1.3	[ ] (f)(5) *Optional & Amb. only*	1.2	1.2
[x] (b)(2)	1.4	1.5			
[x] (b)(3)	1.4	1.2	[ ] (f)(6) *Optional & Amb. only*	1.3	1.0.3
[x] (b)(4)	1.3	1.4			
[x] (b)(5)	1.4	1.7	[ ] (g)(1)	1.6	1.8
[ ] (b)(6) *Inpt. only*	1.3	1.7	[x] (g)(2)	1.6	1.8
[x] (b)(7)	1.4	1.5	[x] (g)(3)	1.3	
[x] (c)(1)	1.6	1.6	[x] (g)(4)	1.2	
[x] (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:

- [x] Ambulatory
- [ ] 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		[x] 136	v3	[ ] 155	
[ ] 22		[x] 117	v2	[ ] 137		[ ] 156	
[ ] 50		[ ] 122		[ ] 138		[ ] 157	
[ ] 52		[ ] 123		[ ] 139		[ ] 158	
[ ] 56		[ ] 124		[ ] 140		[ ] 159	
[ ] 61		[ ] 125		[ ] 141		[ ] 160	
[x] 62	v2	[ ] 126		[ ] 142		[ ] 161	
[ ] 64		[ ] 127		[ ] 143		[ ] 163	
[x] 65	v3	[ ] 128		[ ] 144		[ ] 164	
[ ] 66		[ ] 129		[ ] 145		[ ] 165	
[ ] 68		[ ] 130		[x] 146	v2	[ ] 166	
[x] 69	v2	[ ] 131		[ ] 147		[ ] 167	
[ ] 74		[ ] 132		[x] 148	v2	[ ] 169	
[x] 75	v2	[ ] 133		[ ] 149		[ ] 177	
[ ] 77		[ ] 134		[x] 153	v2	[ ] 179	
[ ] 82		[ ] 135		[ ] 154		[ ] 182	

Inpatient CQMs							
CMS ID	Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
[ ] 9		[ ] 71		[ ] 107		[ ] 172	
[ ] 26		[ ] 72		[ ] 108		[ ] 178	
[ ] 30		[ ] 73		[ ] 109		[ ] 185	

Inpatient CQMs							
CMS ID	Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
☐ 31		☐ 91		☐ 110		☐ 188	
☐ 32		☐ 100		☐ 111		☐ 190	
☐ 53		☐ 102		☐ 113			
☐ 55		☐ 104		☐ 114			
☐ 60		☐ 105		☐ 171			

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 Document History

Version	Description of Change	Date
07-Feb-2014	Modified layout	07-Feb-2014
20-Nov-2013	Updated test tool sections	20-Nov-2013
25-Oct-2013	Corrected numbering of 3.2.8 section	25-Oct-2013
15-Oct-2013	Modified layout slightly	15-Oct-2013
01-Oct-2013	Initial Version	01-Oct-2013

2014 Edition Test Report Summary

MedEvolve
EHR • RCM • PM • eRx

February 24, 2014

To whom it may concern,

I, Carla Hudson, am an authorized company representative and hereby attest that MedEvolve, LLC, located at 1115 West 3rd Street Little Rock, Arkansas has completed certification criterion 170.314.g.3, Safety Enhanced Design.

Furthermore, I attest that the documents provided, Usability Test Report and MedEvolve Specification for User Centered Design Process, are true and accurate to the best of my knowledge.

Sincerely,

Carla Hudson

2014 EHR Certification Project Manager

MedEvolve Modification Definition

MU2

170.314.g.3.1
(Safety Enhanced Design)

Revision Date	Initials	Revision Comment
02/21/2014	cjh	Initial Draft

MedEvolve Modification Definition
170.314.g.3.1

Definition Statement:
This specification outlines the MU2 measure 170.314.g.3.1

ISO 13407 outlines four essential activities in a user-centered design project:

- **Requirements gathering** – Understanding and specifying the context of use
- **Requirements specification** – Specifying the user and organizational requirements
- **Design** – Producing designs and prototypes
- **Evaluation** – Carrying out user-based assessment of the site

Jeffrey Rubin describes usability objectives as: [1]

- **Usefulness** - product enables user to achieve their goals - the tasks that it was designed to carry out and/or wants needs of user.
- **Effectiveness (ease of use)** - quantitatively measured by speed of performance or error rate and is tied to a percentage of users.
- **Learnability** - user's ability to operate the system to some defined level of competence after some predetermined period of training. Also, refers to ability for infrequent users to relearn the system.
- **Attitude (likeability)** - user's perceptions, feelings and opinions of the product, usually captured through both written and oral communication.

Modification Description:
This document provides a high level overview of the User-Centered Design (UCD) process and practices used by the MedEvolve design team during the development of the MedEvolve EHR, specifically in the following modules:

- § 170.314(a)(1) Computerized provider order entry
- § 170.314(a)(2) Drug-drug, drug-allergy interaction checks
- § 170.314(a)(6) Medication list
- § 170.314(a)(7) Medication allergy list
- § 170.314(a)(8) Clinical decision support
- § 170.314(b)(3) Electronic prescribing
- § 170.314(b)(4) Clinical information reconciliation

[1] Jeffrey Rubin, Handbook of Usability Testing: How to Plan, Design, and Conduct Effective Tests, John Wiley and Sons, Inc., 1984

The MedEvolve design team does not follow one specific industry standard user centered design process; rather, we have borrowed principles and processes from many. MedEvolve, as a whole, emphasizes a culture of customer partnership and putting our customers at the center of every business decision. In particular, the team responsible for the end design has used several bibliographic references over the years to help fine tune processes geared toward keeping the customer first; the two references cited above, as well as, books such as, "Why software Sucks…and what you can do about it" by Davis S. Platt and "Good to Great" by Jim Collins.
The process described below is a meld of over 150 years combined industry experience in software development and implementation, customer service and support.

Feature Requests
Feature and enhancement requests are provided by our customers, formalized, and presented to an internal Software Review Board. This board considers all enhancement requests based on the benefit that the request brings to our customers, including the requesting customer and our other customers. Enhancement requests from customers are often formalized by our sales, trainers, or support staff, which have sufficient experience with our customers and our product to visualize how the enhancement request could be implemented in such a way as to provide the most benefit to the most customers.

Requirements Analysis
Before prototyping or designing the enhancement, analysis is performed to determine the exact requirements and prerequisites for the enhancement. This analysis includes a line of business analysis, business rules analysis, data analysis (what data is needed for reporting, what data is required to provide the requested output/feedback), analysis of third-party interfaces used or needed, and analysis of benefit to customer.

Modification Definition
Once the requirements are known, a modification definition is written. The definition is often written from the perspective of the customer requesting the enhancement, often written by someone with implementation experience, such as someone from sales, training, or support. The modification definition is not a technical document, but rather a document describing the feature requested and the benefits to the customer. A software developer takes the modification definition and determines the technical requirements and often creates a feature prototype that is presented to the design team, including the requesting customer for additional feedback.

Development Testing and QA
Once the feature or enhancement has completed the steps above, it is added to the development cycle. Please refer to MedEvolve Modification Definition 170.314.g.4 Quality Management System Specification, to learn about the internal testing and quality assurance cycle of a product enhancement or feature.

Customer Testing and Approval

Towards the end of the development testing and QA cycle, the feature or enhancement is installed at selected customer sites for BETA testing. The BETA testing customers are selected based on interest in and/or perceived benefit from the feature or enhancement. The BETA testing phase allows for the customer to use the feature in a real practice/workflow setting for which the feature was intended. The development team works closely with the customer during this phase to gather feedback on usability, efficiencies and user satisfaction.

MedEvolve EHR Version 6.0 Usability Test Report

Report bases on ISO/IEC 25062:2006 Common Industry Format for Usability Test Reports

MedEvolve EHR 6.0

Date of Usability Test: February 21, 2014

Date of Report: February 22, 2014

Report Prepared by: Carla Hudson and Donna Reed

Table of Contents

Executive Summary

A usability test of MedEvolve EHR, version 6.0, complete EHR was conducted on February 21, 2014 in the MedEvolve, LLC corporate offices. The purpose of this test was to test and validate the usability of the current user interface and provide evidence of usability in the EHR under Test (EHRUT).

During the usability test, 7 healthcare providers and other intended users matching the targeted demographic criteria served as participants used the EHRUT in simulated but representative tasks.

This study collected performance data on 7 tasks typically conducted on an EHR:

- Creating a Patient Medication List
- Creating a Patient Medication Allergy List
- Computerized Provider Order Entry (CPOE)
- Electronic Prescribing
- Drug-Drug, Drug-Allergy Interaction Checks
- Clinical Information Reconciliation
- Clinical Decision Intervention

Prior to the start of the usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form (included in Appendices 1-2); they were instructed that they could withdraw at any time. Participants had prior experience with an EHR. The administrator introduced the test and instructed the participants to complete a series of 7 tasks (given one at a time) using the EHRUT. Each Task was preceded with a brief explanation of the general purpose of the task and a brief instructional training. During the testing, data loggers recorded performance data on paper.

The following types of data were collected for each participant:

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

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire.

In accordance with the examples set forth in the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records,* were used to evaluate the usability of the EHRUT. Following is a summary of the performance and rating data collected on the EHRUT.

Measure Task	*N*	Task Suc-cess	Path Deviation	Task Time (Minutes)		Errors	Task Ratings 5=Easy
	#	Mean	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. (a.6) Record, change and access patient medication lists (active and history)	7	57%	3 (24/21)	4.25 (1.62)	17 (38/21)	0 (0)	4.14 (1.07)
2. (a.7) Record, change and access patient allergy lists (active and history)	7	86%	1 (22/21)	2.83 (3.90)	16 (30/14)	0 (0)	4.29 (1.89)
3. (a.1) Record, change and access medications, labs and xray.	7	86%	2 (65/63)	7.00 (2.37)	24 59/35	0 (0)	4.71 (.76)
4. (b.3) Electronically create prescriptions	7	100%	0 (21/21)	2.00 (.79)	4 (18/14)	0 (0)	5.00 (0)
5. (a.2) Show drug-drug, drug-allergy interaction checks	7	86%	0 (35/35)	3.17 (.90)	8 (22/14)	0 (0)	4.71 (.76)
6. (b.4) Electronically reconcile patient medication, problem and drug allergy lists.	7	57%	1 (22/21)	3.50 (4.04)	7 (21/14)	0 (0)	4.14 (1.07)
7. (a.8) Set up and activate a Clinical Decision Intervention for a Problem List, Medication List, Drug Allergy List, Demographics, Lab Tests and Results, Vitals and one combination of the above.	6	50%	2 (86/84)	9.00 (.89)	3 (35/32)	0 (0)	3.50 (2.24)

The results from the System Usability Scale scored the subjective satisfaction with the system based on the performance with these tasks to be 74%. [1]

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

Major findings:

Overall, the user verbal feedback was very positive from the users. Minor improvements were expressed.

Area s for improvement:

Noted some small inconsistencies in forms and functionality, for example 2 different search dialogues launched from same form were organized differently. This caused some confusion. Patient medications were presented to the user in 2 different areas – patient history and current plan. The forms were very similar – users thought they should be able to perform same functions from both forms, caused some confusion. Not all orders could be viewed in the same area.

Form size issues with reconciliation.

[1] See Tullis, T. &Albert, W. (2008). Measuring the User Experience. Burling, MA: Morgan Kaufman (p.149). Broadly interpreted , scores under 60 represent systems with poor usability; scores over 08 would be considered above average.

Introduction

The EHRUT tested for this study was MedEvolve EHR, version 6.0. Designed to present medical information to healthcare providers in ambulatory settings across multiple specialties, the EHRUT consists of several modules that can be customized to optimize the users and providers daily workflow. The usability testing attempted to represent realistic exercises and conditions.

The purpose of this study was to test and validate the usability of the current user interface and provide evidence of usability in the EHRUT. To this end, measures of effectiveness, efficiency and user satisfaction, such as time on each task and rating ease of completion, were captured during the usability testing.

Method

Participants

A total of 7 participants were tested on the EHRUT. Participants in the test were Administrative assistants, clinical assistants, clinical technicians and a registered nurse. Participants were recruited by MedEvolve, LLC. The participants had no direct connection to the development of or organization producing the EHRUT. The following end-user characteristics were provided to a Practice administrator to aid in the recruiting the intended participants: (Appendix 1)

Clinical and/or clinical administrative experience (Various years of experience)

Users that would perform any of the following types of tasks in their daily workflow

- Order Labs or X-Rays/Images
- Order Medications
- Prescribe Medications
- Create or modify a patient problem list
- Create/ modify a patient's allergy list
- Create /modify patient's medication list
- Perform a clinical reconciliation of patient medications, problems and allergies

Participants were given the opportunity to have the same orientation and level of training as the actual end users would have received.

For the test purposes, end-user characteristics were identified and used to solicit and screen potential participants.

The following is a table of participants by characteristics, including demographics and professional experience. Participant names were replaced with Participant IDs so that an individual's data cannot be tied back to individual identities.

Participant ID	Gender	Age	Occupation/Role	Professional Experience
1	F	45	Administrative Assistant	5+ years
2	F	29	Clinical Assistant	3 years
3	F	34	X-Ray Technician	9.5 years
4	F	25	PT Tech	9 months
5	F	58	Registered Nurse	13 years
6	F	56	Clinical Assistant	13 years
7	F	30	Clinical Assistant	7 years

Study Design

Overall, the objective of this test was to uncover areas where the application performed well – that is, effectively, efficiently, and with satisfaction – and areas where the application failed to meet the needs of the participants. The data from this test may serve as a baseline for future tests with an updated version of the same EHR. In short, this testing serves as both a means to record or benchmark current usability, but also to identify areas where improvements must be made.

During the usability test, each participant was provided with the same instructions. The system was evaluated for effectiveness, efficiency and satisfaction as define by measures collected and analyzed for each participant:

- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's comments
- Participant's satisfaction ratings of the system

Tasks

A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with the HER. The tasks listed below were prioritized in accordance with the risk associated with user error.

1. Creating a Patient Medication List
2. Creating a Patient Medication Allergy List
3. Computerized Provider Order Entry (CPOE)
4. Electronic Prescribing
5. Drug-Drug, Drug-Allergy Interaction Checks
6. Clinical Information Reconciliation
7. Clinical Decision Intervention

Procedures

Upon arrival, participants were greeted and assigned a participant ID. Each participant reviewed and signed an informed consent and release form (See Appendices 1-2). A representative from the team witnessed the participants' signature.

To ensure that the test ran smoothly, the usability administrator and 2 data loggers participated in this test. The administrator moderated the session including administering instructions and tasks.

For each task the participants were given a written copy of the task. Task timing began once the administrator finished the task description. The task time was stopped once the participant indicated they had successfully completed the task. Scoring is discussed below.

Following the session, the administrator gave the participant the post-test questionnaire (see Appendix 6).

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

Test Location

The test was performed at MedEvolve, LLC corporate offices. The test facility was large conference area with 2 large tables equipped with a computer for each participant. All participants, administrator and data loggers were in the test room together.

Test Environment

The EHRUT would typically be used in a healthcare office or facility. In this instance, the testing was conducted in a conference area setup with a 2 large tables equipped with a computer per participant. A large video monitor used for demonstration and instructional purposes. For the testing, the computers used were six Dell laptops and one Dell workstation, running various versions of Microsoft Windows, from Windows XP to Windows 7. The participants used a mouse and keyboard when interacting with the EHRUT.

The minimum screen resolution supported by the EHRUT is 1024x768. The laptops and workstation used for testing were composed of a variety of models and used a variety of screen resolutions, ranging from 1024x768 to 1680x1050. All displays used a 32-bit color depth. The application was set up by the MedEvolve staff according to our install and system set up standards. The application itself was running on a client/server platform using a test database on a [LAN] connection.

Technically, the system performance was representative to what actual users would experience in a field implementation.

Test Forms and Tools

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

1. Informed Consent
2. Non-Disclosure Agreement
3. Test Guide
4. Post-test Questionnaire
5. Data Logging Sheet

Examples of these documents can be found in Appendices [1-6]. Verbal comments and errors were captured and manually recorded on the moderator's guide.

Participant Instructions

The administrator read the following:

Thank you for participating in this study. Your input is very important. Our session today will last about 3 hours. During that time you will use an instance of an electronic health record. You will be asked to complete 7 tasks using the system and answer some questions. You should complete the tasks as quickly as possible. Please try to complete the tasks on your own following the instructions as closely as possible. Please note that we are not testing you, we are testing the system, therefore if you have difficulty all this means is that something needs to be improved in the system.

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. Please be honest with you opinions. All of the information that you provide will be kept confidential and your name will not be associated with you comments at any time. Should you feel it necessary you are able to withdraw at any time during the testing.

Participants were given 7 tasks to complete. Tasks are listed Test guide in Appendix [5]

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 the users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction.

To this end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing. The goals of the test were to assess:

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

Data Scoring

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

Measures	Rationale and Scoring
Effectiveness: Task Success	A task was counted as a 'Success' if the participant was able to achieve the correct outcome, without assistance, within the time allotted. The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage. Task times were recorded for successes. The observed task times were divided by the total number of times the tasks were successfully completed to determine a median time of efficiency.
Effectiveness: Task Failures	If the participant abandoned the task or performed the task incorrectly, the task was counted as a 'Failure'. No task times were taken for errors. The total number of errors was calculated for each task and then divided by the total number of times that task was attempted.
Efficiency: Task Deviations	The participant's steps through the application were observed. 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. The path was compared to the optimal path.
Efficiency: Task Time	Each task was timed from when the administrator said "begin" until the participant said 'done'. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task.
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question, as well as, a post-session questionnaire.

Results

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 instruction had their data excluded from the analyses. [No data was excluded]

The usability testing results for the EHRUT are detailed below. The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance.

Measure / Task	*N*	Task Success	Path Deviation	Task Time (Minutes)		Errors	Task Ratings 5=Easy
	#	Mean	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. (a.6) Record, change and access patient medication lists (active and history)	7	57%	3 (24/21)	4.25 (1.62)	17 (38/21)	0 (0)	4.14 (1.07)
2. (a.7) Record, change and access patient allergy lists (active and history)	7	86%	1 (22/21)	2.83 (3.90)	16 (30/14)	0 (0)	4.29 (1.89)
3. (a.1) Record, change and access medications, labs and xray.	7	86%	2 (65/63)	7.00 (2.37)	24 59/35	0 (0)	4.71 (.76)
4. (b.3) Electronically create prescriptions	7	100%	0 (21/21)	2.00 (.79)	4 (18/14)	0 (0)	5.00 (0)
5. (a.2) Show drug-drug, drug-allergy interaction checks	7	86%	0 (35/35)	3.17 (.90)	8 (22/14)	0 (0)	4.71 (.76)
6. (b.4) Electronically reconcile patient medication, problem and drug allergy lists.	7	57%	1 (22/21)	3.50 (4.04)	7 (21/14)	0 (0)	4.14 (1.07)

7. (a.8) Set up and activate a Clinical Decision Intervention for a Problem List, Medication List, Drug Allergy List, Demographics, Lab Tests and Results, Vitals and one combination of the above.	6	50%	2 (86/84)	9.00 (.89)	3 (35/32)	0 (0)	3.50 (2.24)

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with these tasks to be: 74%.[2] The percentage was derived by applying the following formula to the SUS results:

Scoring SUS

- For odd items: subtract one from the user response.
- For even-numbered items: subtract the user responses from 5
- This scales all values from 0 to 4 (with four being the most positive response).
- Add up the converted responses for each user and multiply that total by 2.5. This converts the range of possible values from 0 to 100 instead of from 0 to 40.

Broadly interpreted, scores under 60 represent systems with poor usability scores over 80 would be considered above average. [3]

[2] Sauro, Jeff: Citing Source:[http://www.measuringusability.com/sus.php] para4. February 2, 2011
[3] See Tullis, T. &Albert, W. (2008). Measuring the User Experience. Burling, MA: Morgan Kaufman (p.149).

Discussion of the Findings

Effectiveness

Effectiveness refers to the extent to which the product behaves in the way that users expect it to and the ease with which users can use it to do what they intended. This is usually measured quantitatively with error rate.

In our testing, we found that the 36 out of 48 user tasks (74%) were accurately completed within the time allotted, without assistance.

The results of our testing show that the majority of users found the software to behave as they expected and their ratings show that they found it to be easy to use, with only 9 path deviations in a total of 48 total tasks (19%) that deviated from the optimal path.

Efficiency

Efficiency relates to the quickness with which the user's goal can be accomplished accurately and completely and is usually a measure of time.

36 out of 48 user tasks were completed accurately within the time allotted, without assistance. Optimal times are factored by 1.25% to accommodate the fact that the participants were not expert users, which results in total observed times being 24% over total optimal times.

Satisfaction

The user's perceptions, feelings and opinions of the product were captured through both written and oral questioning.

Users were asked to rate and rank the MedEvolve 6.0 EHR software product. 84% expressed average or above satisfaction with the software tasks they were asked to perform. This is based on the number of answers (maximum of 70 answers for 7 testers responding to 10 questions each) on the System Usability Scale, as follows – with a Rating of 5 being the most desirable on odd questions and a Rating of 1 being the most desirable on the even questions:

System Usability Scale Results

Rating: Question#:	**1**	**2**	**3**	**4**	**5**
1	0	0	1	1	5
2	2	3	0	2	0
3	0	1	0	2	4
4	4	1	1	0	1
5	0	0	1	2	4
6	2	3	0	2	0
7	0	1	1	1	4
8	1	2	1	2	1
9	0	1	1	1	4
10	3	0	3	1	0

Risk Analysis

Task 1 shows the most path deviations by users, but we feel this represents the fact that this was the first test with a new system, rather than the Task itself being prone to user errors. Once the users were familiar with this Task (and therefore more accustomed to the system), the path deviations were minimal.

The path deviations on Task 3 were because medication orders and lab and x-ray orders are done on separate forms (Medical History and Orders) - and a couple of users initially incorrectly clicked on Orders to order medications.

The path deviations on the other tasks were primarily in the third party application where medications are actually electronically ordered. It looks and acts differently than the EHR software being tested, so there were a few deviations while users got familiar with that functionality.

There were no major user errors, and only one application error when clicking on a external link that MedLine directed the user to as relevant. This will error be addressed so that the user will be shown a message instead of being kicked out of our software.

The nature of the path deviations by the testers was expected for new users and we have plans to address their concerns and questions as new users with our extended help system. The only adverse consequences due to the path deviations would be slightly extended times to complete tasks.

Major Findings

The major findings interpreted from the verbal report of the participants and the observations from the data loggers were as follows:

84% of those who tested the software expressed above average satisfaction with the product and stated they were able to perform the tasks with ease and a minimum of frustration.

All in all, users were satisfied with the navigation, content, presentation and interaction of the software.

Areas for Improvement

There were a few areas that the users expressed a wish to see improvement on. Their suggestions were noted and will be implemented into the design, if they weren't already planned. Among the suggestions were to include additional elements on the screen, continuity of search dialog boxes and the presentation of information on the screen.

Appendices

The following appendices include supplemental data for this usability test report. Following is a list of the appendices provided:

1. Recruitment Screening Questionnaire
2. Participant Demographics
3. Non-Disclosure Agreement
4. Informed Consent Form
5. Example Data Logger Sheet
6. Example Test Guide
7. System Usability Scale Questionnaire

Appendix 1: Recruitment Screening Sheet

Professional Demographics

What is your current position and title?

How long have you held this position?

Would you perform any of the following types of tasks in your daily workflow?

- Order Labs or X-Rays/Images
- Order Medications
- Prescribe Medications
- Create or modify a patient problem list
- Create/ modify a patient's allergy list
- Create /modify patient's medication list
- Perform a clinical reconciliation of patient medications, problems and allergies

Appendix 1: Non-Disclosure Agreement

Non-Disclosure Agreement

THIS AGREEMENT is entered into as of _____, *2014*, between _____ ("the Participant") and the testing organization MedEvolve, LLC located at 1115 West 3rd Street, Little Rock, AR 72201.

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 MedEvolve, LLC, or otherwise acquired by the Participant, in the course of today's study.

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

Any information the Participant acquires relating to this product during this study is confidential and proprietary to MedEvolve, LLC 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 not disclose this confidential information obtained today to anyone else or any other organizations.

Participant's printed name: _____

Signature: _____ Date: _____

Appendix 2: Informed Consent

Informed Consent

MedEvolve, LLC 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.

Agreement

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

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 the data collected from this study may be shared outside of MedEvolve, LLC and MedEvolve, LLC's client. 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:** _____

Appendix 3: Participant Demographics

Participant Demographics

Gender: _____

Age: _____

Occupation/Role: _____

Years of experience: _____

Main Responsibilities: _____

Appendix 4: Data Logger Sheet

Administrative Worksheet

Task #1: Patient Medication List

Enable a user to electronically record, change and access a patient's active medication list as well as medication history.

- **Observations: Record comments from Participants, any errors received**

Participant # ***Comments***

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

General comments regarding this task:

_____

_____

_____

_____

Administrative Worksheet

Task #2: Patient 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.

- **Observations: Record comments from Participants, any errors received**

Participant # ***Comments***

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

General comments regarding this task:

_____

_____

_____

_____

Administrative Worksheet

Task #3: Computerized Provider Order Entry (CPOE)

Enable a user to electronically record, change and access the following order types:

- Medications
- Laboratory
- Radiology/Imaging

➢ **Observations: Record comments from Participants, any errors received**

Participant # ***Comments***

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

General comments regarding this task:

_____

_____

_____

Administrative Worksheet

Task #4: Electronic Prescribing

Enable a user to electronically create prescriptions and prescription related information for electronic transmission.

- **Observations: Record comments from Participants, any errors received**

Participant # ***Comments***

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

General comments regarding this task:

_____

_____

_____

_____

Administrative Worksheet

Task #5: Drug-Drug, Drug-Allergy Interaction Checks

Before a medication order is completed and acted upon during 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.

- **Observations: Record comments from Participants, any errors received**

Participant # ***Comments***

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

General comments regarding this task:

_____

_____

_____

_____

Administrative Worksheet

Task #6: Clinical Reconciliation

Enable a user to electronically reconcile the data that represent a patient's active medication, problem and medication allergy list.

- **Observations: Record comments from Participants, any errors received**

Participant # ***Comments***

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

General comments regarding this task:

_____

_____

_____

_____

Administrative Worksheet

Task #7: Clinical Decision Intervention and Configuration

Enable a limited set of users to select or activate one or more electronic clinical decision support interventions and reference resources based on each one of the following data:

- Problem List
- Medication List
- Medication allergy list
- Demographics
- Lab Tests and values/results
- Vital Signs

- **Observations: Record comments from Participants, any errors received**

Participant # ***Comments***

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

General comments regarding this task:

_____

_____

_____

MedEvolve EHR Version 6.0 Usability Test Report

Test Participant 1

Table of Contents

Product under Test:	MedEvolve EHR Version 6.0
Date of Usability Test:	February 21, 2004
Location of Test:	MedEvolve, LLC Corporate Office
	1115 West 3rd Street
	Little Rock, AR 72201

General Purpose

The intention of the usability testing is to help MedEvolve design team in determining the effectiveness, efficiency and satisfaction with which the intended user can achieve their tasks in the context of product use.

Overall, we are interested in how easy or difficult the system is to use, what in it would be useful to you, and how we could improve it.

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

Task #1: Patient Medication List

Enable a user to electronically record, change and access a patient's active medication list as well as medication history.

Task scenario:

Patient **Andy Anderson *(account # P1A)*** is an existing patient. During a previous encounter she was prescribed Simvastatin 20 mg tablet to be taken by mouth once daily.

For today's visit, electronically record the following medication for Patient **Andy Anderson *(account # P1A)***

- Lorazepam 0.5 mg tablet by mouth three times daily

Modify the patient's medication list.

- Discontinue use of Simvastatin 20 mg
- Change the frequency of Lorazepam 0.5 mg tablet from three time s daily to every six hours.

Verify the patient's medication list accurately reflects:

- Larazepam 0.5 mg tablet by mouth every six hours
  Status: Active
- Simvastatin 20 mg tablet by mouth once daily
  Status: Discontinued

Task Start Time: _____

Task End Time: _____

Success:

___ Easily completed
___ Completed with difficulty or help: Describe below
___ Not completed

Comments*:*

Task #2: Patient 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.

Task scenario:

Patient **Andy Anderson *(account # P1A)*** is an existing patient. During previous encounters it was recorded that she was allergic to Sulfasalazine with a reaction of wheezing and Penicillin V with a reaction of dizziness.

For today's visit, electronically record the following medication allergy for **Andy Anderson *(account # P1A).***

- Add Codeine with reaction of skin rash

Modify the patient's medication list.

- Inactivate the status of Sulfasalazine
- Delete Penicillin V
- Add Penicillin G with a reaction of dizziness

Verify the patient's active medication allergy list accurately reflects:

- Penicillin G
  Reaction: Dizziness
- Codeine
  Reaction: Skin rash

Verify the patient's medication allergy list history accurately reflects:

- Inactive Sulfasalazine
  Reaction: Wheezing
- Penicillin G
  Reaction: Dizziness
- Codeine
  Reaction: Skin rash

Task Start Time: _____

Task End Time: _____

Success:

___ Easily completed
___ Completed with difficulty or help: Describe below
___ Not completed

Comments*:*

Task #3: Computerized Provider Order Entry (CPOE)

Enable a user to electronically record, change and access the following order types:

- Medications
- Laboratory
- Radiology/Imaging

Task scenario:

Patient **Betty Boop (account # P1B)** is an existing patient. During today's visit you will order 3 medications, 2 laboratory tests, an MRI and X-ray.

Electronically order the following medications for Patient **Betty Boop (account # P1B)**

- Metoprolol Tartrate 50 mg tablet by mouth once daily; dispense 60, 2 refills
- Warfarin Sodium 5 mg tablet by mouth once daily; dispense 60, 0 refills

Electronically order the following labs for Patient **Betty Boop (account # P1B)**

- Drugs of abuse 5 panel in urine by screen (LOINC 65750-2)
- Hemoglobin A1c/hemoglobin.total in blood (LOINC 4548-4)
- Lipid 1996 panel in serum or plasma (LOINC 24331-1)

Electronically order the following images for Patient **Betty Boop (account # P1B)**

- MRI chest w/o contrast (CPT 71550)
- Radiologic exam ankle 2 views (CPT 73600)

Modify the patient's medication order.

- Change Metoprolol Tartrate to 25 mg tablet by mouth once daily; dispense 60, 1 refill (To do this you will need to delete the original order and re-order)

Modify the patient's lab order.

- Change drugs of abuse 5 panel to Troponin l.cardiac in serum or plasma (LOINC 10839-9)

Modify the patient's imaging order.

- Change MRI w/o contrast to MRI chest w/o & w/ contrast materials (CPT 71552)

Verify the patient's orders accurately reflect:

Medications:

- Metoprolol Tartrate 25 mg tablet by mouth once daily; dispense 10, 1 refill
  Status: Active
- Warfarin Sodium 5 mg tablet by mouth once daily; dispense 60, 0 refills
  Status: Active

Laboratory:

- Troponin I.cardiac in serum or plasma (LOINC 10839-9)
  Status: Pending
- Hemoglobin A1c/hemoglobin.total in blood (LOINC 4548-4)
  Status: Pending

- Lipid 1996 panel in serum or plasma (LOINC 24331-1)
  Status: Pending

Imaging:

- MRI chest w/o & w/ contrast materials (CPT 71552)
- Radiologic exam ankle 2 views (CPT 73600)

Task Start Time: _____

Task End Time: _____

Success:

___ Easily completed
___ Completed with difficulty or help: Describe below
___ Not completed

Comments*:*

Task #4: Electronic Prescribing

Enable a user to electronically create prescriptions and prescription related information for electronic transmission.

Task scenario:

Patient **Carl Carlton *(account # P1C)*** is an existing patient. During today's encounter it is decided to prescribe the following medications:

For today's visit, electronically record the following medication for Patient **Carl Carlton *(account # P1C)***

- Azithromycin 500 mg tablet by mouth once daily; dispense 10, 0 refill, substitutions are allowed
- Norvasc 5 mg tablet by mouth once daily; dispense 30, 1 refill, substitutions are allowed

Task Start Time: _____

Task End Time: _____

Success:

___ Easily completed
___ Completed with difficulty or help: Describe below
___ Not completed

Comments*:*

Task #5: Drug-Drug, Drug-Allergy Interaction Checks

Before a medication order is completed and acted upon during 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.

Task scenario:

Patient **Donald Donaldson (account# P1D)** is an existing patient that has a recorded allergy to Penicillin and has previously been prescribed Neomycin. During a today's encounter it is decided to prescribe the following medication:

- Ceftin 500 mg tablet by mouth once daily; dispense 10, 0 refill, substitutions are allowed

Verify that interventions were automatically displayed.

A user with the appropriate security will adjust the severity level of drug-drug interventions.

Access the medication order for **Donald Donaldson (account# P1D)**

Verify that interventions are not displayed.

Task Start Time: _____

Task End Time: _____

Success:
___ Easily completed
___ Completed with difficulty or help: Describe below
___ Not completed

Comments*:*

Task #6: Clinical Reconciliation

Enable a user to electronically reconcile the data that represent a patient's active medication, problem and medication allergy list.

Task scenario:

Patient **Emmy Emmerson *(account # P1E)*** is a returning patient that has not been seen by the provider for long period. She has provided a list of her current medication, medication allergy and problem history.

During today's visit, you will compare the external list provided by **Emmy Emmerson *(account # P1E)*** with your practice's record for Emmy Emmerson and reconcile the medication, medication allergy and problem*s* into a single list.

List # 1 (Existing):

Medications Allergies	**Medications**	**Problems**
Sulfamethoxazole	Zocor 40 mg	Persistent Asthma
Penicillin V	Simvastatin 20 mg	

List #2 (Import):

Medications Allergies	**Medication**	**Problems**
Sulfasalazine	Simvastatin 20 mg	Coronary arteriosclerosis
Penicillin	Lorazepm 0.5 mg	Benign prostatic hyperplasia
Carbamazepine	Insulin Glargine 10 units	Atrial fibrillation

Merged List:

Medications Allergies	**Medication**	**Problems**
Sulfamethoxazole	Zocor 40 mg	Persistent Asthma
Penicillin V	Simvastatin 20 mg	Coronary arteriosclerosis
Sulfasalazine	~~Simvastatin 20 mg~~	Benign prostatic hyperplasia
~~Penicillin~~	Lorazepm 0.5 mg	Atrial fibrillation
Carbamazepine	Insulin Glargine 10 units	

Verify the current Medication, Medication allergy and Problem lists reflect the following consolidated information:

Medications Allergies	**Medication**	**Problems**
Sulfamethoxazole	Zocor 40 mg	Persistent Asthma
Penicillin V	Simvastatin 20 mg	Coronary arteriosclerosis
Sulfasalazine	Lorazepm 0.5 mg	Benign prostatic hyperplasia
Carbamazepine	Insulin Glargine 10 units	Atrial fibrillation

Task Start Time: _____

Task End Time: _____

Success:
___ Easily completed
___ Completed with difficulty or help: Describe below
___ Not completed

Comments*:*

Task #7: Clinical Decision Intervention and Configuration

Enable a limited set of users to select or activate one or more electronic clinical decision support interventions and reference resources based on each one of the following data:

- Problem List
- Medication List
- Medication allergy list
- Demographics
- Lab Tests and values/results
- Vital Signs

Task scenario:

Create a clinical decision support intervention with resource information for each of the data elements listed above. Activate each rule for a select set of users.
Evaluate the intervention by creating an encounter for each of the following patients. During their encounter you will be alerted to review a Clinical decision intervention. Note the intervention Information and resource information.
Patient accounts: P1F, P1G, P1H, P1I, P1J, P1K, P1L, P1M

Task Start Time: _____

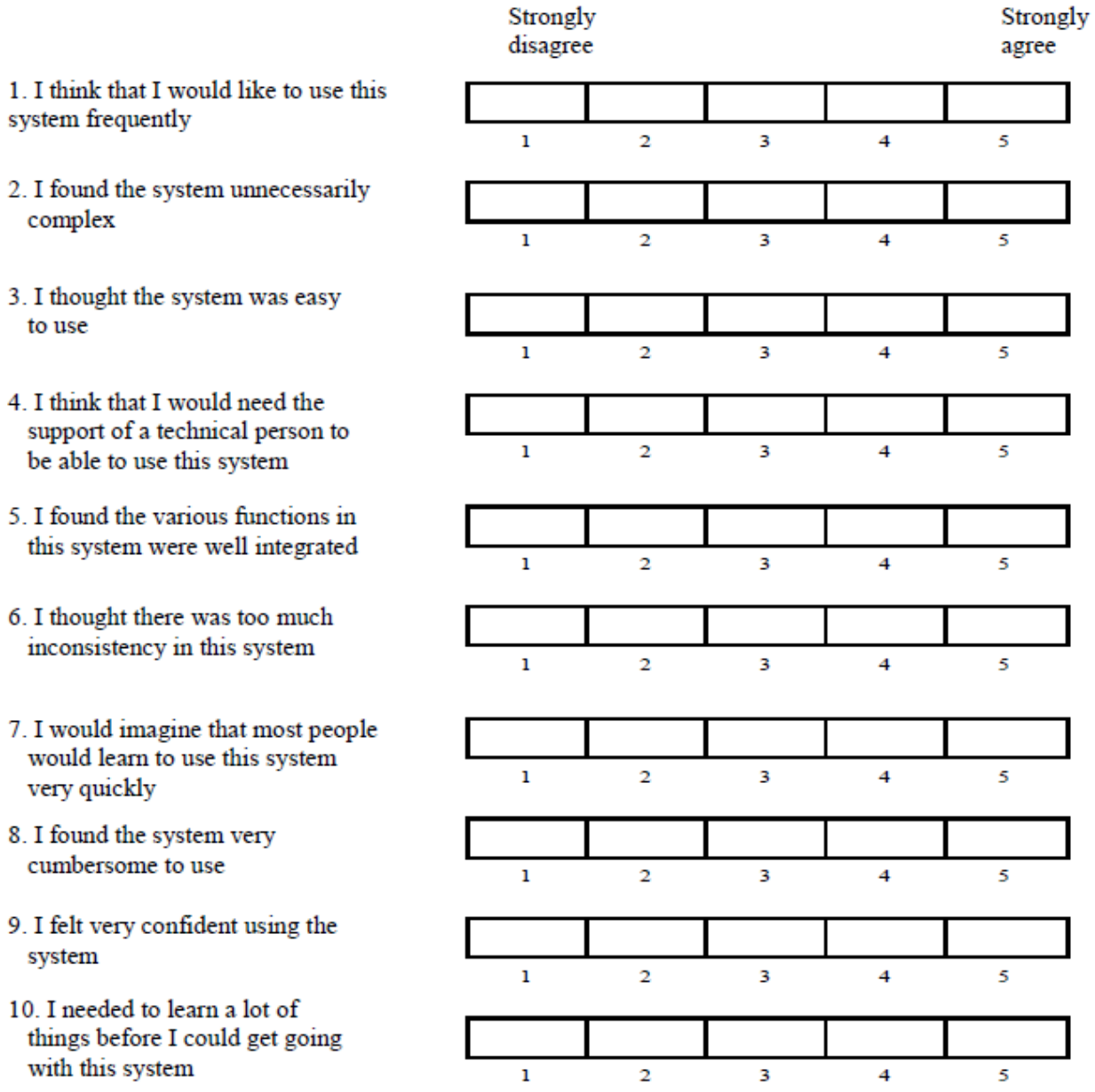
Task End Time: _____

Success:
___ Easily completed
___ Completed with difficulty or help: Describe below
___ Not completed

Comments*:*

Appendix 6: System Usability Scale Questionnaire

System Usability Scale Questionnaire



MedEvolve
EHR • RCM • PM • eRx

February 24, 2014

To whom it may concern,

I, Carla Hudson, am an authorized company representative and hereby attest that MedEvolve, LLC, located at 1115 West 3rd Street Little Rock, Arkansas has completed certification criterion 170.314.g.4, Quality Management System.

Furthermore, I attest that the document provided, MedEvolve Specification for Quality Management System, is true and accurate to the best of my knowledge.

Sincerely,

Carla Hudson

2014 EHR Certification Project Manager

MedEvolve Modification Definition

MU2

170.314.g.4
(Quality Management System)

Revision Date	Initials	Revision Comment

MedEvolve Modification Definition

MU2

170.314.g.4
(Quality Management System)

11/26/2013 jmr Initial Draft

MedEvolve Modification Definition
170.314.g.4

Definition Statement:
This specification outlines the MU2 measure 170.314.g.4.

From the ASQ Glossary:

Quality management (QM): The application of a quality management system in managing a process to achieve maximum customer satisfaction at the lowest overall cost to the organization while continuing to improve the process.

Quality management system (QMS): A formalized system that documents the structure, responsibilities and procedures required to achieve effective quality management.

Modification Description:
This document provides a high level overview of the homegrown Quality Management System used during the development of the MedEvolve EHR.

The team responsible for the design, development, and quality of the MedEvolve EHR has over 150 years of experience with multiple software development and quality processes. The system described below is a meld of these experiences and has improved over the past 15 years as our processes have improved.

Several books have been used to help us find processes that work well, such as "Code Complete" by Steve McConnell, "A Practical Guide to Feature-Driven Development" by Stephen Palmer, and "Best Kept Secrets of Peer Code Review" by Jason Cohen. We strive to keep our customer first with the perspective of "Why Software Sucks… and what you can do about it" by David S. Platt. And the excellent resource "Good to Great" by Jim Collins has helped us transform our development processes and team from good to great.

Through the years, we've reviewed the IBM Rational Unified Process, Rational ClearCase Process, as well as the process models described by the traditional waterfall process, agile processes, and even extreme processes. Our team has implemented elements of each process, where those elements work well and improve our homegrown process. This is part of our effort to continually improve our development and quality processes.

Feature Requests
Feature and enhancement requests are provided by our customers, formalized, and presented to an internal Software Review Board. This board considers all enhancement requests based on the benefit that the request brings to our customers, including the requesting customer and our other customers. Enhancement requests from customers are often formalized by our sales, trainers, or support staff, who have sufficient experience with our customers and our product to visualize how the enhancement request could be implemented in such a way as to provide the most benefit to the most customers.

Requirements Analysis

Before prototyping or designing the enhancement, analysis is performed to determine the exact requirements and prerequisites for the enhancement. This analysis includes a line of business analysis, business rules analysis, data analysis (what data is needed for reporting, what data is required to provide the requested output/feedback), analysis of third-party interfaces used or needed, and analysis of benefit to customer.

Modification Definition

Once the requirements are known, a modification definition is written. The definition is often written from the perspective of the customer requesting the enhancement, often written by someone with implementation experience, such as someone from sales, training, or support. The modification definition is not a technical document, but rather a document describing the feature requested and the benefits to the customer. A software developer takes the modification definition and determines the technical requirements and often creates a feature prototype that is presented to the design team for additional feedback.

Change Tracking

All changes to the MedEvolve EHR software are tracked in our Change Management System, Borland StarTeam. A Change Request is created for all defects found and enhancements requested. Any modification definitions or other specifications available, including screenshots and prototypes, are attached to the Change Request.

A Change Request has the following workflow:

- Created by our QA Team. As the owner of the Change Request, the responsibility of the CR always reverts back to our QA team when the CR is ready for review or approval.
- Responsibility is initially assigned to our development manager, who will assign the Change Request to the ideal developer based on developer experience and scheduling.
- Implemented and tested by the developer. All source code changes checked into StarTeam require comments describing the change and all source code changes are tracked by Change Request, so we can report on the exact source code changes that were implemented for any given Change Request.
- Once the developer has tested the change and checked the change in, the responsibility of the CR reverts back to our QA team for testing.
- If the QA team finds the CR fails for any reason, a description of the findings are added to the CR and the responsibility is changed back to the developer initially assigned to implement the change.
- If the CR passes QA testing, a repeatable test case is created in an automated testing tool and the CR is marked as verified fixed.

Peer Review

As changes are checked in and before a build is completed, changes are peer reviewed by senior developers by comparing the change against the previous version. StarTeam and Beyond Compare greatly simplify the process of performing these code reviews by using a virtual machine that is dedicated to our code review process. Comments, questions, and suggestions may be added to the CR's description, which are automatically emailed to the developer.

As developer coding mistakes and patterns emerge, our QA team provides feedback to the development manager to assist each developer identify these patterns and learn to identify them and avoid them in the future.

Build / Change Tracking

Build labels are used in StarTeam to track which CRs are included in each build, the build number that a CR was last tested, the build number that addressed each CR, and the build number where the CR was verified fixed. This provides excellent feedback to our QA team, documentation, support, and implementation teams, so our teams are aware of the changes and improvements available in each build.

Automated Testing

Unit tests are created for application server methods to ensure the server method behaves as expected, performs the expected result, and returns the expected output.

Automated tests are created per CR using SmartBear's TestComplete automated functional testing tool. Builds are tested against a compiled set of previously created automated tests to help ensure future changes do not cause bug regression.

Our stress test framework stresses the middle-tier application servers under a simulated load of hundreds of users making server requests simultaneously.

Documentation

Once a change has been implemented and approved by our QA team, the change is provided to our documentation team along with any supporting specifications or screenshots. Our documentation team then verifies the change works as expected and updates our context sensitive online documentation, providing the user with information about the new change or feature.

170.314(d)(2) Auditable events and tamper-resistance

Overview

All data compiled by the auditor is stored within a Microsoft SQL Server database. The ability to access the MedEvolve database directly is unavailable to the end-user of the MedEvolve EHR Software.

Every user within the MedEvolve EHR software requires a unique user ID in order to access the functions of the software. All users have assorted security privileges that allow access to certain functionality within the application. In addition to privileges that may be specific to any given piece of functionality within the software, all secure functionalities have three basic levels of privilages: Browse, Modify, and Delete rights. These 3 security rights help shape what a user may do within the MedEvolve EHR Software.

VE170.314(d)(2) – 4.01

Within the MedEvolve EHR, a user must be granted modify rights specifically to the Auditor functionality in order to be able to enable or disable the Auditing of patient data. Without such rights, the user may see the auditor's status, but will be unable to change, overwrite, or delete it. Thus the status' change will not occur and be recorded within its history logs.

When the status of the Audit Log has been modified, a record of the status change is recorded in an electronic database. The user may review the history of the Auditor's status, but changing, overwriting, or deleting these records is impossible without editing the data being stored within the electronic database.

VE170.314(d)(2) – 5.01

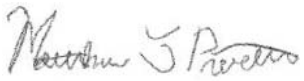
As stated in the "Overview" section of this document, the Audited data is secured in an electronic database. When the user wishes to see the log, the user is presented a windows form containing a grid that shows all events audited within the parameters specified. The grid cannot be edited and changes cannot be made to these records.

There is no file that is genetrated that a user can save or view outside of MedEvolve. The only way for a user to alter the audit log history would be to log into the database itself and perform direct manipulation of the history.

Someone with direct access to the database server could potentially alter the audit log using SQL UPDATE statements. In particular, system and network administrators often have administrative access to SQL Server in order to configure and monitor network jobs and troubleshoot system issues. If there is suspicion of audit log tampering, MedEvolve has a utility that we can use to search for changes that were made to the audit log using a database connection other than our application. All changes made by our application are made via a SQL login that is only known to a few MedEvolve employees. Therefore, it is easy to locate any tampering that has occurred in the audit log.

MedEvolve, LLC does not condone nor support direct manipulation of the data within the database by non MedEvolve employees.

By signing this document, I declare that all information presented in this document is accurate at the date and time indicated.



Matthew Pruett
Software Developer

MedEvolve Modification Definition

MU2

170.314.d.7
(Encryption of Data at Rest)

Revision Date	Initials	Revision Comment
11/26/13	jmr	Initial Draft

MedEvolve Modification Definition
170.314.d.7

Definition Statement:
This specification outlines the MU2 measure 170.314.d.7.

Modification Description:
This specification describes the current behavior of the MedEvolve EHR software regarding MU2 measure 170.314.d.7 and the encryption of data at rest on end-user devices.

The MedEvolve EHR client application requests data, including electronic health information, from our middle-tier application server. The middle-tier is a custom written application server that uses Embarcadero Delphi's DataSnap protocol to package data requests into a proprietary binary data packet. The specification for the data packet is defined by Embarcadero's Middle-tier Distributed Application Services specification.

The middle tier submits the data request to a relational database management system, typically Microsoft SQL Server, packages the data requested in the proprietary binary data packet, and returns the data packet back to the client application. The client application in turn unpacks the data packet as an in-memory record set.

The MedEvolve EHR client application never stores or caches these data packets on the end-user device. Everything is stored in memory and is lost when the application is terminated, either through a normal exit or an abnormal termination.

There is an application log that is stored on the end-user device that tracks application activity and error reports. At no time is electronic health information stored in this log file.

Client/Server Modifications
This specification requires no changes to the current behavior of the MedEvolve EHR client or middle-tier server applications.

MedEvolve Modification Definition
170.314.d.7

Prerequisites:
This specification has no prerequisites.

Additional Considerations:
This specification has no additional considerations.

Potential Problems:
The design team did not identify any problems associated with this modification.

Estimated Development Time:
The estimated development staff time is zero hours.

Evidence of Completion:
This definition will be complete when QA can perform the new functionality based on the Modification definition.