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:	Rush-Copley Bar Code Medication Administration
Product Version:	V1.0
Domain:	Inpatient
Test Type:	Modular EHR

1.2 Developer/Vendor Information

Developer/Vendor Name:	Copley Memorial Hospital, Inc.
Address:	2000 Ogden Ave Aurora IL 60504
Website:	www.rushcopley.com
Email:	laura.looney@rushcopley.com
Phone:	630-236-4376
Developer/Vendor Contact:	Laura Looney

Part 2: ONC-Authorized Certification Body Information

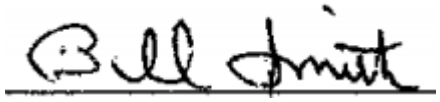
2.1 ONC-Authorized Certification Body Information

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


7/10/2014
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

2.3 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: KAM-070914-2597

Test Date(s): 7/9/2014

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:

Kyle Meadors	Test Proctor
ATL Authorized Representative	**Function/Title**
 7/10/2014	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

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)	☐ §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)	☐ §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	☐ §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	☐ §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*]	
(e)(1)(ii)(A)(2)	☐ §170.210(g) Network Time Protocol Version 3 (RFC 1305)	☐ §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)	☐ §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
- [ ] Inpatient
- [x] 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		☐ 71		☐ 107		☐ 172	
☐ 26		☐ 72		☐ 108		☐ 178	
☐ 30		☐ 73		☐ 109		☐ 185	
☐ 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.

2014 Edition Test Report Summary

Rush-Copley Medical Center
2000 Ogden Avenue, Aurora, IL 60504

We, Copley Memorial Hospital, confirm that the information in the document Barcode Administration Usablity Evaluation is accurate and complete.

Signature: Brenda VanWyhe
Printed Name: Brenda Van Wyhe
Title: Senior Vice President of Finance and Chief Financial Officer
Date: 7/1/14

eMAR Usability Test Report of Rush Copley Bar Code Medication Administration, Version 1.0

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

Rush Copley Bar Code Medication Administration, Version 1.0

Date of Usability Test:	December 9, 2009 through March, 2010
Date of Report:	May 23, 2014
Report Prepared By:	Laura Looney

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EXECUTIVE SUMMARY

A usability test of Rush Copley Bar Code Medication Administration, Version 1.0 was conducted four (4) times, starting in December of 2009 through March of 2010 at Copley Memorial Hospital by Judi Bonomi, RN, MS, MSN, OCN, NE-BC, the Director of Director,Cancer Care Center and Inpatient Nursing. During the usability test, 4 RNs on day shift and 4 RNs on night shift measured 6 medication passes for 97 passes total. All of the data was collected during actual use of the production systems.

This study collected performance data three (3) times. Once pre-implementation, once one month post-implementation and once three (3) months post-implementation. The data collected was time needed to deliver medication to a patient-beginning when RN intends to obtain the medication and ending when medication administration is documented; whether or not the system functioned as expected. Additional critical measures for successful implementation of the software used were Medication Variance Reports, Overtime, and the Press-Ganey Patient Satisfaction report.

The initial purpose of these tests were done as a research project to be submitted to the Institutional Review Board. (included in Appendix 1). The findings were in general that the impact on nurse's time to administer medications post implementation of bedside bar coded medication administration tehcnology was unchanged. Additionally, the system worked as designed and there was no evidence of impact on overtime, no medication variances related to the 5 rights during the 3-month interval, and the patient satisfaction was in the 92nd percentile rank in the Press-Ganey database at 96.

The study was designed by Judi Bonomi, RN, MS, MSN, OCN, NE-BC, the Director of Director,Cancer Care Center and Inpatient Nursing and coordinated by Spring Cha, RN. The participants were solicited with a Power Point presentation asking for volunteers (Appendix 2) , the measurements were done by an investigator and sub-investigator for start time, type of medication delivery (PO, IV, other), scheduled or PRN medication, and end time. Subjects were de-identified on the data collection tools (Appendix 3). Each participant signed an informed consent (Appendix 4) with age range and years of practice. Each participant was allowed to decline participation at the time the investigator showed up.

INTRODUCTION

Copley Memorial Hospital, Inc. certified the usability of the Rush Copley Bar Code Medication Administration, Version 1.0 during the period it was first implemented. Each of the five rights was tested in the test environment prior to implementation and the time to perform those functions were measured prior to go-live, and two times post go-live. Each participant completed at least 6 medication passes, half on day shift and half on the night shift. The software functioned as expected during the study to ensure the five rights were being met.

METHOD

Participants

A total of 10 RNs participated in the time study for medication passes. Participants were recruited by Judi Bonomi, RN, MS, MSN, OCN, NE-BC, the Director of Director,Cancer Care Center and Inpatient Nursing, the owner and designer of the test by using a power point presentation (Appendix B). Participants all had the same orientation to the system as all RNs were given prior to go-live.

End-users characteristic were de-identified except for age range and number of years of practice. These two elements were retained to determine if either of those factors contributed to the outcome for future investigation, if needed.

Both day and night shift were equally represented.

STUDY DESIGN

The objective of the this test was to determine the usability of the system as it relates to time demands on the RN doing medication administration with patients. Prior to go-live, the 5 rights were thoroughly tested by both the vendor, McKesson Technologies, as well as by the project team of Information Systems analysts, Pharmacy and RN testers.

The original intent of this study was a research study submitted and approved by the Institutional Review Board (Appendix 1).

TASKS

All tasks that are required from the beginning of a medication pass until the time the administration was documented in the system being evaluated were included. Unrelated tasks (interruptions and other non-essential tasks) were also recorded, noted and later removed from the related task time.

PROCEDURES

The investigator and sub-investigator noted the days and shifts of the participants and set a schedule to record the measures while they were working. The participants signed an informed consent (Appendix 4) and were allowed to decline if the patient did not agree to have the investigator and sub-investigator present.

The six medication passes measures were reported on a Data collection tool (Appendix 3) by the investigator and later that information was summarized for presentation. The participant was designated as one of four day shift or night shift RNs (circled Subject# 1, 2, 3 or 4 on the tool). Start time, type of medication, number of medications given, the medication was "S", scheduled, or "P" PRN, end time, whether or not the medication was available, if there were interruptions and how long, and was the software functional (5 rights).

Each participant was sent a thank you letter from Judi Bonomi, RN, MS, MSN, OCN, NE-BC, the Director of Director,Cancer Care Center and Inpatient Nursing, regarding their participation and that the findings would be presented at the Research Poster day, as well as formally presenting a paper on the findings in the future.

TEST LOCATION

The test was performed in the inpatient departments with actual medication passes and in the production system. Only the participant was in the room with the patient with the investigator monitored within view of the participant, but to be intrusive to the process.

TEST ENVIRONMENT

The test was done in the same environment that all RNs utilize every day. The participants were not given any special instructions and were asked to perform all of their tasks as usual. The investigators were to be ignored and the investigators were to be observers only.

TEST FORMS AND TOOLS

During the usability test, two documents were used. They were:

1. Informed Consent

2. Data Collection Tool – Day Shift and Night Shift

They can be found in Appendix D and C.

PARTICIPANT INSTRUCTIONS

The participants had access to the Power Point presentation (Appendix B) that explained that the timings for medication passes from beginning until end were completed prior to using the Bar Code Medication Administration software and that the study was to do the same timings post implementing the Bar Code Medication Administration software. The timings should reflect the "actual" time rather than just measuring tasks. It was important to compare beginning until end to see if the times and the functions were usable.

USABILITY METRICS

The goal was to determine if the system supported a high level of usability for all users. To measure this, time, expected functionality (5 rights) and patient satisfaction were measured during this time period.

1. Efficiency: Compare the time took from beginning of a medication pass until the time the administration was documented pre-implementation vs. after go-live
2. Effectiveness: Compare medication variance reports for the same time periods.
3. Satisfaction: Compare patient satisfaction (Press Ganey) scores for the same time periods, as well as note if software functioned as expected was recorded on the data collection tool.

RESULTS

DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above.

Table of observations-Data listed in minutes: seconds

Nurse	Pre	1 month post-no cabinet	3 months post-cabinets	Comments
D RN 1	4:03	5:53	7:38	Interruption with phone call in last observation
D RN 2	5:30	6:49	8:35	Interruption with phone call in last observation
D RN 3	6:54	8:57	4:58	Removed one data point that

				had extended interruption
D RN 4	7:21	5:08	4:10	
N RN 1	6:51	7:00	6:18	
N RN 2	7:48	8:02	6:06	
N RN 3	4:08	5:25	3:33	
N RN 4	7:15	5:53	7:15	Removed one data point that had extended interruption
Average time all participants at data point	6:14	6:38	6:04	

Summary of data:

1. Only medication pass times increased post implementation were those with extended interruptions
2. Almost all participants returned to baseline post implementation or shorter time to pass medication post implementation
3. Software functioned 100% of the time
4. Medication unavailable x 2-each time increased medication pass time noted, pixies malfunction x 1-increased medication pass time
5. Slight increase in time with bedside bar coding at 1 month and no medication cabinet
6. Experience or age of nurse did not impact time to pass medication

EFFICIENCY

The time it took to do a med pass prior to the system being implemented vs. after implementing the system was minimal at one month and then became stable and the same after the one month mark. As the nursing staff became more familiar with the system over time, the time it took to do a med pass stayed the same, neither increasing or decreasing.

EFFECTIVENESS

The software functioned as expected 100% of the time. Nurses did not require additional training or guidance after the initial training to be proficient in the use of bar code administration, and the use of the system was over the goal of 95%. Mediation errors decreased during that same time period as expected.

SATISFACTION

Satisfaction scores for both nurses using the Bar Code Administration software and Pharmacy satisfaction scores did not change. The improved medication errors met the needs of those who approved the project, pharmacy, and care givers.

APPENDICES

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

1. Research project submitted to the Institutional Review Board.
2. Power point presentation
3. Data collection tools
4. Participant informed consent

It is important to note, these are examples only.

5.1.1 DRAFT

5/31/01

Rush-Copley Medical Center
Better ways to better health

RESEARCH INVOLVING HUMAN SUBJECTS

NEW PROJECT

APPLICATION INSTRUCTIONS

Submit application materials to:

Institutional Review Board

c/o: Office of VP of Medical Affairs

630-978-4983

Read the instructions carefully.

Please answer all questions as completely as possible.

Improper submissions can result in delayed reviews.

1) Submit the following materials: the original signed and dated submission form, one copy of the protocol, consent documents, advertisements or recruitment materials. (The protocol may be a research proposal, grant, a pharmaceutical protocol or another similar document.)

2) For studies involving investigational drugs or devices, submit a copy of the investigational drug or device brochure and a completed drug data or device form.

3) One copy of any scripts, letters, questionnaires or survey instruments and advertisements to be used in this study.

New Project

Rush-Copley Medical Center Human Subject Review Form

Principal Investigator: Judi Bonomi

Department: Nursing Administration_____

Department Address: Rush-Copley Medical Center

Email Address: jbonomi@rsh.net

Telephone/Pager #/Fax Number: 978-6200-extension 6203

Study Coordinator/Additional contact person for this study: Judi Bonomi

Study Coordinator/Additional contact phone and email address: Spring Cha, RN, scha@rsh.net

Project Title: "The impact on the time of the nurse to administer medications with a bedside bar coded medication administration implementation

_____

☐ Expedited IRB Review Exemption from Continuing IRB Review X Full IRB Review

6 Total human subjects to be enrolled in this study: 8		**Gender Breakdown (if known)**	M:	F:
If your project plans include any of the following study subjects, indicate below and include the proposed number of subjects:		**If you are using any of the following, please indicate below:**		
☐ Minors (under 18) Ages:		☐ Existing Data/Records:		
☐ Pregnant Women/Fetuses		☐ Pathology/Diagnostic Specimens:		
☐ Cognitively Impaired				
☐ Prisoners				
☐ Other				

FUNDING INFORMATION:

Project Sponsor(s):	Advancing the Profession and Innovations Congress	☐ Departmental Funding	
Grant/Contract Application Date(s):			
Funding Agency Number(s):		Other ORA numbers related to this project:	
☐ Part of a Training, Center or Program Project Grant		Project Director:	

Assurance

The undersigned assures that the protocols involving human subjects described in this application are complete and accurate, and are consistent with applicable protocols submitted to external funding agencies. All protocol activities will be performed in accordance with Rush-Presbyterian-St. Luke's Medical Center, and State and Federal regulations. No activities involving the use of human subjects will be initiated without prior review and approval by the Rush Institutional Review Boards.

_____

Signature of Principal Investigator Date Signature of Department Chair Date

_____

***If Student Project: Signature of Supervising Faculty/Date: _____**

FOR IRB USE ONLY: EXPEDITED PER 45 CFR 46.110 PART _____

EXEMPT PER 45 CFR 46.101 PART _____

WAIVER OF ANY/SOME OF THE ELEMENTS OF CONSENT PER 45 CFR 46.116 C OR D_____

WAIVER OF DOCUMENTATION OF CONSENT PER 45 CFR 46.117 C _____

_____

Approved by IRB Chair or Designated Reviewer/Date

FDA INFORMATION: (applies to drug/device/biologic studies requiring FDA approval)

☐ **INVESTIGATIONAL NEW DRUG: IND Number and Name: _____**

☐ **INVESTIGATIONAL DEVICE EXEMPTION: IDE Number and Name: _____**

☐ **BIOLOGIC PRODUCT Number and Name: _____**

If you have completed any of the above information, submit one copy of the drug brochure or device information with this proposal.

Investigators and other key personnel involved with human subjects on this project, include responsibilities and the names of those who will obtain consent. Include site(s) where the study will be conducted.

Judi Bonomi will obtain the consent. The study will be conducted on the Med Surg/Cancer Care unit of the hospital. Spring Cha will assist with data collection. A poster asking for volunteers will be placed in the unit break room.

ABSTRACT: Provide a non-technical summary of this project. Do not provide extensive experimental details.

A time study to measure the time to administer medications prior to implementation of the software system for bedside bar coded medication administration, and the time to administer medications 1 month and 3 months post implementation.

RESEARCH PLAN: The research plan should include sufficient information needed for evaluation of this project independent of any other document. When appropriate include inclusion and exclusion criteria, and plans for monitoring the safety of subjects. In treatment protocols, clearly state which procedures are considered standard treatment and which are research procedures.

The study will involve a time measurement of the nursing staff. Four nurses from the day shift and four nurses from the night shift will be asked to participate, seeking volunteers. They will have 5 medication administrations observed at each time point.

Does this study have an independent Data Safety Monitoring Group? ☐ Yes X No

If yes, provide the name of the DSMG and their location.

RECRUITING AND CONSENT PROCESS: The process for obtaining informed consent must be considered by the IRB. This includes who, when, how, and any special circumstances pertinent to the process. The Principal Investigator of the project is responsible for all aspects of the consent process regardless of any delegation of duty. Please provide detailed information regarding how subjects will be identified, who will approach them regarding potential research participation, and in cases of subjects lacking decisional capacity, when and how the Illinois Health Care Surrogate Act will be used.

A poster, seeking volunteers to participate, will be placed in the nursing unit breakroom. The staff who volunteer must consent to participate. The first 4 volunteers in each shift will be offered the opportunity to participate.

RISKS: The IRB must review and find that research risks are reasonable in relation to anticipated benefits to subjects or others. Consideration should be given to all risks. For example: physical risks, psychological risks, emotional risks, legal risks, social risks or financial risks, risks related to privacy and confidentiality.

There may be anxiety on the staff participants due to the observation and timing of the task.

PROCEDURES TAKEN TO MINIMIZE RISKS:

The observer will keep a distance and not interrupt the participant.

BENEFITS: Describe potential benefits to study participants and/or mankind. Note: Compensation is not a benefit.

To allow nurses to understand the impact on their shift when using patient safety technology.

ALTERNATIVES TO PARTICIPATION: (include currently accepted treatments or practices, in some cases it may be appropriate to include non-participation as an alternative)

Nurses will use the system as designed without being observed.

CRITERIA FOR EXEMPTION FROM CONTINUING IRB REVIEW

No more than minimal risk and one or more of the following:

☐ **(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the among instructional techniques, curricula, or classroom management methods.**

☐ **(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:**

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

☐ **(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:**

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ **(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.**

☐ **(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:**

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ **(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.**

Note: The IRB, at its discretion, retains the right to require continuing review when warranted by the nature of the research and/or inclusion of vulnerable subject populations.

CRITERIA FOR EXPEDITED HUMAN SUBJECTS REVIEW

Research Activities involving:

a) No more than minimal risk

b) the categories in this list apply regardless of age of subjects, except as noted

c) standard requirements for informed consent (or waiver, alteration or exception) apply

☐ Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

☐ Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows: (a) from healthy, non-pregnant adults, who weigh at least 110 pounds. For these subjects, amounts drawn may not exceed 550 ml in an 8 weeks period and no more than 2 times per week; or (b) from other adults and children, considering age, weight, and health, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml/kg in an 8-week period and no more than 2 times per week.

☐ Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a)hair and nail clippings, in a non-disfiguring manner; (b) deciduous teeth at the time of exfoliation; (c) permanent teeth if patient care indicates a need for extraction; (d) collection of excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) collection of both supra- and subgingival dental plaque and calculus, provided the collection procedure is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☐ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed they must be cleared/approved for marketing.

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

(b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencelphalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, ultrasound, infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

☐ Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

☐ Collection of data from voice, video, digital or image recordings made for research purposes.

☐ Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Note: The IRB, at its discretion, retains the right to require full committee review when warranted by the nature of the research and/or inclusion of vulnerable subject populations.

Investigator Agreement

1. I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights or welfare of subjects.
2. I agree to personally conduct or supervise the described investigation.
3. In studies involving drugs or devices, I agree to inform any subjects or any persons used as controls, that the drugs or devices being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent and IRB review and approval are met.
4. I agree to report to the sponsor and the IRB adverse experiences that occur in the course of the investigation.
5. In studies involving drugs or devices, I have read and understand the information in the investigator's drug or device brochure, including potential side effects and risks of the drug or device.
6. I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
7. I agree to maintain adequate and accurate records in accordance with the regulations and to make those records available for inspection in accordance with the regulations.
8. I ensure that I will submit this project for initial and continuing review and approval of the investigation.
9. I agree to report promptly to the IRB any and all changes in the research activity and all unanticipated problems involving risk to human subject or others.
10. Additionally, I will not make any changes to the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
11. I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements found in the regulations.

The IRB and/or the Office of Research Affairs may make audit any or all IRB approved protocols to inquire about study progress, inspect accrued consent documents, inspect accrued data, and/or observe the consent process that is used. The Principal Investigator must cooperate fully with the IRB or Office of Research Affairs staff making such visits.

Signature of Principal Investigator Date

APPENDIX 2

Interested in becoming a research participant?

- I am conducting a time study on the time to administer medications prior to and post implementation of the EMAR and bedside bar coded medication administration
- I am asking for 4 nurse volunteers from day shift and 4 from night shift
- Contact Judi Bonomi at x6203 or jbonomi@rsh.net if you are interested by November 18th!

APPENDIX 3

Data collection tool-Day shiftObservation 1=pre implementation

Subject# 1 2 3 4

Start time	Type of medication	Number of medications to be given	Scheduled (S) or PRN (P)	End time	Medication available	Interruptions	Software functional
#1							
#2							
#3							
#4							
#5							
#6							

APPENDIX 4
Informed Consent

You are being asked to participate in a research study to quantify the time spent on medication administration prior to and post implementation of a bedside bar coded medication administration and EMAR.

The study observations will be conducted in November, prior to implementation, and in January (1 month post implementation) and March (3 months post implementation). The observations will be conducted during 5 medication passes on your shift, noting start time, type of medication administered, route of administration, interruptions, medication availability and equipment malfunction.

If you agree to participate, the data collected will be de-identified and your identity confidential. Four nurses will be participating from the day shift, and 4 nurses from the night shift. Scheduled and PRN medication administration will be observed. You can withdraw from participation with no consequences. Participants will be asked to provide demographic information on age and years in practice as a nurse.

Data will be presented to the hospital Nursing Leadership, and Professional Advancement and Innovations Congress, as well as the team involved in the pilot program, and Nursing Congresses. No identifying information will be presented.

Your signature indicates your consent to participate in the study described above.

Signature_____

§170.314(g)(4) Quality Management System

There are two components to the Quality Management System utilized by Copley Memorial Hospital for the Rush-Copley Bar Code Medication Administration v1.0. The first is the contractual agreement we have with McKesson Corporation for the licensing and on-going maintenance agreement for the AdminRx product. The Rush-Copley Bar Code Medication Administration v1.0 is the McKesson AdminRx v10.1.

The McKesson AdminRx v10.1 is not modularly certified with the McKesson EMR, so we had to self certify the module. Other than that, McKesson provides the Quality Management System to ensure the system, database, reports, and all aspects of the AdminRx v10.1 is accurate. Our contract with McKesson provides a method for assisting with any issues through their help desk and ticketing system. All issues have been resolved timely and adequately.

The other Quality Management System utilized by Copley Memorial Hospital is our own internal method for providing accurate enhancements, fixes and updates to systems. We have a complete change management structure in place that defines how to make change requests, who can make them, who has access to make changes, the requirement to test changes in the test environment, change control committee, and end user acceptance controls.

The Quality Management System also includes policy that protects security of the systems in the datacenter, the security of who has access to the systems, and who has access to the applications. All requests, changes and access is documented and audited annually.