CALIFORNIA STATE UNIVERSITY SAN MARCOS

PROJECT SIGNATURE PAGE

PROJECT SUBMITTED IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE

MASTER OF SCIENCE

IN

NURSING

PROJECT TITLE: PILOT STUDY: BCMA BARRIERS AND WORKAROUNDS AMONG ICU/CCU NURSES

AUTHOR: Darshel Marie Ontkean, BSN, MSNc, RN

DATE OF SUCCESSFUL DEFENSE: April 21, 2015

THE PROJECT HAS BEEN ACCEPTED BY THE PROJECT COMMITTEE IN
PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF
SCIENCE IN NURSING.

Dr. JoAnn Daugherty, PhD., RN, CNL  
PROJECT COMMITTEE CHAIR

Dr. Denise Boren, PhD., RN  
PROJECT COMMITTEE MEMBER

5/4/15
DATE

5/4/15
DATE
BAR CODE MEDICATION ADMINISTRATION (BCMA) WORKAROUNDS AMONG ICU/CCU NURSES

A Research Grant Proposal

Presented to the faculty of the School of Nursing
California State University, San Marcos

Submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

in

Nursing

Family Nurse Practitioner

by

Darshel M. Ontkean MSNc, BSN, RN

SPRING
2015
Student: Darshel Marie Ontkean

I certify that this student has met the School of Nursing format requirements, and that this project is suitable for shelving in the Library and credit is to be awarded for the project.

[Signature]
Dr. Denise Boren, Director

[Date]

School of Nursing
College of Education, Health, and Human Services
California State University San Marcos
Abstract

of

PILOT STUDY: BCMA BARRIERS AND WORKAROUNDS AMONG ICU/CCU NURSES

A RESEARCH GRANT PROPOSAL

by

Darshel Marie Ontkean MSNc, BSN, RN

Statement of Problem: Since the Institute of Medicine (IOM) presented their findings in 1999 on medical errors, the healthcare industry has dedicated tremendous effort to addressing the problem of ensuring patient safety. Great strides have been made in achieving the IOM goal through standards and guidelines implemented throughout the healthcare industry. However, adverse drug events (ADEs) are still of serious concern, and continue to occur despite instituting interventions, including the eight rights of medication administration (Bonsall, 2011). Especially concerning are the ADEs at the endpoint of medication administration which is one of the most final and therefore dangerous actions performed. In ICU/CCU nurses work with one of the most vulnerable patient populations at risk for serious harm from medication errors. Bar code scanning for medication administration (BCMA) provides a viable solution to preventing errors. The BCMA has had a strong, positive reception, and hospitals have seen a significant reduction in medication errors. However, barriers to workflow with the BCMA have prompted nurses to develop workarounds, undermining the purpose of the technology to prevent medication errors.

Purpose: The goal of this pilot study is to develop a survey tool that specifically focuses on the causes of the workarounds by nurses. Information obtained from the survey will highlight areas that may require redesign of the BCMA. Securing an effective BCMA system will produce higher compliance increasing patient safety.

Sources of Data: Surveys of nurses in three Southern California Hospitals.

Dr. JoAnn Daugherty, PhD, RN, CNL

Date

5/4/15
DEDICATION

I would like to dedicate this work in memory of my late Father, Michael Orville Ontkean, who instilled within our family an intellectual curiosity and a love of academic pursuit, and to my Mother, Phyllis Therese Ontkean, who has been a constant support and encouraged me to “never give up” through all adversity.

ACKNOWLEDGEMENTS

I would like to acknowledge my dear friend, John K. Davis, for his wisdom, guidance, encouragement, and support throughout the MSN-FNP program. I am thankful for my three children, Alicia, Paul Aaron, and Michelle, for their love and support of Mom through my ongoing pursuit of nursing knowledge.

I would like to thank my committee chair, Dr. JoAnn Daugherty, and committee member, Dr. Denise Boren for their guidance and knowledge making the completion of my Master in Nursing, FNP, possible.
# Grant Application

**Department of Health and Human Services**  
**Public Health Services**

---

**Do not exceed character length restrictions indicated.**

1. **TITLE OF PROJECT** (Do not exceed 81 characters, including spaces and punctuation.)  
   Pilot Study: BCMA Barriers and Workarounds Among ICU/CCU Nurses

2. **RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION**  
   No Yes  
   (If “Yes,” state number and title)

3. **PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR**

   **3a. NAME** (Last, first, middle)  
   Ontkean, Darshel, Marie

   **3b. DEGREE(S)**  
   BSN RN

   **3c. POSITION TITLE**  
   PCU RN

   **3d. MAILING ADDRESS** (Street, city, state, zip code)  
   24451 Leafwood Dr.  
   Murrieta, CA. 92562

   **3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT**  
   PCU

   **3f. MAJOR SUBDIVISION**

   **3g. TELEPHONE AND FAX** (Area code, number & extension)  
   TEL 951-473-7381  
   FAX:

   **E-MAIL ADDRESS:**  
   ontke001@cougars.csusm.edu

4. **HUMAN SUBJECTS RESEARCH**

   **4a. Research Exempt**
   No Yes  
   If “Yes,” Exemption No.

   **4b. Federal-Wide Assurance No.**

   **4c. Clinical Trial**
   No Yes

   **4d. NIH-defined Phase III Clinical Trial**
   No Yes

5. **VERTEBRATE ANIMALS**

   No Yes

6. **DATES OF PROPOSED PERIOD OF SUPPORT** (month, day, year—MM/DD/YY)

   **From** May 18, 2015  
   **Through** Nov. 20, 2015

7. **COSTS REQUESTED FOR INITIAL BUDGET PERIOD**

   **7a. Direct Costs ($)**

   **7b. Total Costs**

8. **COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT**

   **8a. Direct Costs**

   **8b. Total Costs ($)**

---

9. **APPLICANT ORGANIZATION**

   **Name**

   **Address** TO BE ANNOUNCED

10. **TYPE OF ORGANIZATION**

    - Public:  
      - Federal
      - State
      - Local
    - Private:  
      - Private Nonprofit
    - For-profit:  
      - General
      - Small Business
    - Woman-owned
    - Socially and Economically Disadvantaged

11. **ENTITY IDENTIFICATION NUMBER**

    **DUNS NO.**

    **Cong. Dist.**

12. **ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE**

13. **OFFICIAL SIGNING FOR APPLICANT ORGANIZATION**
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<td>E-Mail:</td>
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</tr>
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</table>

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

<table>
<thead>
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PROJECT SUMMARY (See instructions):

Statement of Problem:

Although the healthcare industry has invested significant effort into decreasing medication administration errors by integrating the Bar Code Medication Administration (BCMA) scanning system into the hospital environment, nurses are creating workaround solutions to workflow barriers inherent within the BCMA system. This has undermined the efficacy of medication error intervention that the BCMA was designed to meet, and ultimately is a patient safety issue. Researchers have discovered the work around solutions used by nurses during their studies to determine the BCMA’s efficacy of reducing medication administration errors. Acknowledging the existence of deviations from the BCMA system safety program has been reported by several researchers, however, the next step in addressing the problem is to develop a tool measuring the barriers causing workarounds by nurses so that interface changes can be made in the BCMA system to ensure nursing compliance, thereby ensuring the highest degree of patient safety.

RELEVANCE (See Instructions)

This research is relevant to the body of nursing science as it builds upon patient safety interventions with medication administration by nurses. Discovery of barriers with the BCMA system and workarounds that are performed by nurses will generate changes with the BCMA to enhance workflow which will induce nurses compliance with the system and heighten patient safety through intervention performance by the BCMA.

PROJECT/PERFORMANCE SITE(S) (if additional space is needed, use Project/Performance Site Format Page)

**Project/Performance Site Primary Location**

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<th>Palomar Health includes Palomar Med. Ctr. &amp; Pomorado Hosp.</th>
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<tr>
<td>Street 1:</td>
<td>2185 Citracado Pkwy.</td>
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<tr>
<td>Street 2:</td>
<td>15615 Pomerado Rd</td>
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<tr>
<td>City:</td>
<td>(1) Escondido (2) Poway</td>
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**Additional Project/Performance Site Location**

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<td>Street 1:</td>
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</table>
**Program Director/Principal Investigator:** Ontkean, Darshel, Marie

**SENIOR/KEY PERSONNEL.** See instructions. *Use continuation pages as needed* to provide the required information in the format shown below. Start with Program Director(s)/Principal Investigator(s). List all other senior/key personnel in alphabetical order, last name first.

<table>
<thead>
<tr>
<th>Name</th>
<th>eRA Commons User Name</th>
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<tr>
<td>Dr. JoAnn Daugherty</td>
<td></td>
<td>CSUSM</td>
<td>Methodologist</td>
</tr>
<tr>
<td>Dr. Denise Boren</td>
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<td>CSUSM</td>
<td>Budget Consultant</td>
</tr>
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**OTHER SIGNIFICANT CONTRIBUTORS**

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**Human Embryonic Stem Cells**

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If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: [http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp](http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp). *Use continuation pages as needed.*

If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used.

**Cell Line**
BCMA WORKAROUNDS: PILOT STUDY GRANT PROPOSAL

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# DETAILED BUDGET FOR INITIAL BUDGET PERIOD

**FROM** May 18, 2015 **THROUGH** Nov. 20, 2015

**List PERSONNEL (Applicant organization only)**

Use Cal, Acad, or Summer to Enter Months Devoted to Project

Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

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## SUBTOTALS

| SUBTOTALS            | 28472.00        |

**CONSULTANT COSTS**

0

**EQUIPMENT (Itemize)**

- Laptop (1) 850.00
- Printer (1) 400.00
- Total: 1250.00

**SUPPLIES (Itemize by category)**

- SPSS data software $1330.00
- Microsoft Office software $317.00
- McAfee Antivirus software $50.00
- Computer Disc backup: $200.00
- Printer Paper, printer ink, misc. supplies: Pens, pencils, highlighters, post-it notes & tabs $200.00.
- Total: 2097.00

**TRAVEL**

- 1.) travel to 3 hospitals
- 2.) 2 conf., reg., airfare, hotels, meals, car, gas for 2 people, 3 days
- Total: 9967.00

**INPATIENT CARE COSTS**

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**OUTPATIENT CARE COSTS**

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**ALTERATIONS AND RENOVATIONS (Itemize by category)**

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**OTHER EXPENSES (Itemize by category)**

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**CONSORTIUM/CONTRACTUAL COSTS**

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**SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD** *(Item 7a, Face Page)*

$ 41786.00

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**TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD**  
$41786.00  

PHS 398 (Rev. 08/12 Approved Through 8/31/2015)  
OMB No. 0925-0001  

**Program Director/Principal Investigator (Last, First, Middle):**  
Ontkean, Darshel, Marie  

---  

**BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD**  
**DIRECT COSTS ONLY**  

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| **SUBTOTAL DIRECT COSTS**  
(Sum = Item 8a, Face Page) | | | | | |
| F&A CONSORTIUM/CONTRACTUAL COSTS | 0 | | | | |
| **TOTAL DIRECT COSTS** | 41786.00 | | | | |

**TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD**  
$41786.00
JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

Supplies:
Laptop computer and dedicated printer are needed to collect, analyze and store data and create correspondence and flyers. The total cost is $1250.00 for the entire project over 6 months. SPSS IBM 21.0 Statistic Pack standard 12 month license can be installed and will be the software product for data management and analysis. Estimated cost is $1330.00 for the year to cover the 6 months of the project. Microsoft Office Professional will be the software product installed for correspondence, flyers, writing of the findings and dissemination of those findings. The cost is $317.00 Total cost for software products for the project is $1647.00.
Antispyware-McAfee estimated cost is $50.00
Computer CD backup to backup data from the hard drive is estimated to cost $200.00.
General office supplies will include printer paper, printer ink, and assorted supplies, estimated to be $200.00.

Travel:
Travel to all 3 hospitals for the survey, and 2 conferences-registration totals $2096.00, for myself and Dr. Daugherty, for 3 days for dissemination of information: 1) San Francisco-airfare for 2 round trip $167.00 each, hotel for two for 3 days, $2850.00, car rental $40.00/day for 3 days $120.00, gas $50.00, meals 3/day for a total $300.00 2.) Washington, DC.- airfare for 2 round trip $816.00, hotel for 2 for 3 days $2850.00, car rental $40.00/day for 3 days $120.00, gas $50.00, meals 3/day $300.00. Total: $9967.00

Personnel:
The research nurse is a novice researcher and an MSNc FNP student at CSUSM. Darshel Ontkean has a BSN with over 7 years in acute care experience, 3 in Med/Surg., over 3 in ICU/CCU, and 1 year in PCU. She will present the project to the ICU/CCU nursing managers for approval and will send the information via e-mail to all potential participants. She will be available for any questions from the potential volunteers regarding the project, confidentiality and IRB as well as oversee data collection. She will review the budget periodically with Dr. Boren and will assist Dr. Daugherty with the data analysis. She will write about the findings as well as disseminate the findings through professional journals of nursing and hospital safety and administration. She will devote at least 16 hours per week on the project for 6 months, at which time the project will be completed. She will be paid $50.00 per hour for a total of $20,800.00.
Dr. Daugherty is PhD prepared with an additional degree in Clinical Nurse Leader. She is a lecturer at CSUSM. Her expertise in the area of statistics and will be the statistician for the project, as well as overseeing the progress and overall direction of the project. She will also oversee the budget until it is complete. She will provide 6 hours as the statistician and will be paid $100.00 per hour for a total of $600.00.
A Research Assistant will work under the direction of Darshel Ontkean and Dr. Daugherty. They will be in the office when Darshel Ontkean is present and will keep the same hours as Darshel Ontkean to assist with mailings, responses, data input, and other assistance. The expected hours are 16 hours per week for 6 months at $17.00/hour for a total of $7,072.00
Specific Aim

Medication administration errors continue to be of significant concern within the healthcare industry. Since 1999 the incidence of medical errors, including medication administration errors, has decreased significantly, but there is still an urgent need to address patient safety through interventions that prevent medication errors.

The ICU/CCU environment has the most vulnerable patient population and the most stressful working conditions for nurses. The BCMA system has been utilized as a viable intervention for medication errors, however, the barriers associated with efficient workflow for nurses has instigated deviations from protocol, thus undermining patient safety, the very reason for the intervention. Researchers discovered the workarounds as a byproduct of establishing the efficacy of the BCMA system in reducing medication errors. The researchers agree that deviations occur, and that the barriers causing the deviations should be studied and a tool should be developed in order to establish the significance of the occurrence of the workarounds. In so doing, changes can be made to the BCMA interface and the system will become a more efficient tool for intervention, gaining the compliance of nurses and promoting patient safety.

Purpose:

The purpose of this study is to identify causes of workarounds used by ICU nurses through a survey. There is insufficient literature focusing on the phenomena of workarounds among ICU nurses, yet it is a critical element for ensuring medication administration safety, especially with one of the most vulnerable patient populations. Reflecting Eindhoven’s belief that one incident has multiple causes; the survey will identify common barriers related to system failure with the use of the BCMA by ICU nurses. Eindhoven’s Classification Model of Latent Failures Causal Tree breaks down system failure into three specific categories, with a fourth for events that do not
have affiliation with a category. The survey is focused on Eindhoven’s two categories: 1.) organization, and 2.) task/technical (van Vuuren, Shea, & Van der Schaaf, 1997). The questions selected for the survey will build on Koppel, et al.’s (2008) research data that lists probable causes in the categories of organization, task, technology, and environment, which corresponds with Eindhoven’s Model.

Data collection via a survey offers the purpose of developing a detailed and accurate measurement tool. A quantitative database of barriers with the BCMA that are the root causes of deviations will be useful for future studies of workarounds. The information is an important step to assist hospitals in developing sound interventions to eliminate BCMA system barriers. Identifying barriers will catalyze analysis, discussion, and create opportunity for systems redesign for a more robust intervention. The end point is increased compliance by nurses using the BCMA to improve patient safety.

**Specific Aim 1:** To develop a survey that effectively discovers the barriers that cause workarounds among ICU nurses, which undermines the patient safety net function of the BCMA.

**Background and Significance**

According to the 2006 report “Preventing Medication Errors” from the Institute of Medicine, (IOM), medication errors cost $3.5 billion in lost productivity, wages, and additional medical expenses per year. The IOM (2006) report brief notes that a “hospital patient can expect on average to be subjected to more than one medication error each day”. Medication errors, also known as adverse drug events (ADE) are considered preventable. Two different reports submitted to the IOM estimate that 380,000-450,000 preventable ADEs occur in hospitals each year (IOM, 2006). The IOM believes that both are underestimated and the number of ADEs is actually closer to 1.5 million each year. Prioritizing the prevention of ADEs has become one of the IOM’s most
important goals. When the IOM’s initial report in 1999 on all medical errors titled “To Err Is Human: Building a Safer Health System”, became public it called for a comprehensive approach to reducing medical errors and improving patient safety. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in their 2005 testimony to Congress stated that hospitals must embrace a systems approach to prevent adverse events (Wreathall & Fastman, 2008). To that end, using the comprehensive approach to find solutions, the healthcare industry has included disciplines from human factors engineering, sociology, organizational psychology, and informatics is a necessary step (Brennan, Gawande, Thomas, & Studdert, 2005).

Kane-Gill, Jacobi, & Rothschild, (2010) report found that up to 29% of all medication errors occur at the point of care in ICUs. Errors occurring at this stage are highly dangerous because they have an increased potential to be lethal. The reason is that the error is less likely to be intercepted, more likely to reach the patient, and is final. The two hospital patient populations identified with the highest incidences of medication errors are; 1) the elderly who have multiple medications and vulnerable health status, and 2) the ICU/CCU due to the complex environment, patient illness severity, increased amount and different types medications, and multiple potentially lethal medication administered, with numerous dosage changes per shift, as well as countless distractions for the nurses (Moyen, Camire, & Stelfox, 2008).

In response to the challenge of eradicating medication errors, nursing, in partnership with the healthcare industry, has developed a system of interventions. Some of the interventions created are: two nurses checking protocols, areas or banners the nurse wears to reduce distraction thereby creating a safety zone for nurses accessing the automated med dispensing system, and self-reports when an error occurs. Importantly, Bonsall (2011) lists eight rights of medication administration: right patient, right medication, right route, right dosage, right time, right
documentation, right reason, and right response. Additionally, technology has contributed through developing smart infusion pumps. These protocols and interventions have helped, but medication errors are still numerous.

Faced with this knowledge, many hospitals have turned to the technology industry. The specific technology of interest was the bar code scanning which has been in use in other industries for years. Automated prevention of medication errors by utilizing the bar code scanning technology prompted several hospital administrators to operationalize the bar code scanning medication administration (BCMA) system. Using the BCMA scanner on the patient’s wrist band, the information is linked to the BCMA computer for confirming the five rights of medication administration. Patient safety is enhanced by the system’s ability to confirm the first five rights and intercept medication errors at the point of care. Nursing has embraced the BCMA, however, it is not a perfect system and nurses have expressed dissatisfaction with the some elements of the system’s workflow design.

Evidence supporting the reduction of medication errors by using the BCMA system has been supported in several studies and hospitals have been strongly urged to make BCMA the protocol for medication administration. Much of the data for the various researches on the BCMA system’s effectiveness in preventing medication error was obtained using direct observation and shadowing of nurses. An unplanned, but significant observation during the studies revealed that nurses were deviating from the BCMA system (Anderson & Townsend, 2010; Koppel, et al., 2008). These deviations, or workarounds, occur due to deficiencies in the system’s workflow design, and many of the nurses consider workarounds as a normal part of using the system. System failures to operate smoothly were barriers for nurses in performing their tasks. These barriers prompt nurses to create adaptations to accomplish their tasks in a timely manner.
Significance to Nursing:

Reducing medication errors is a priority for nursing, hospitals, and for the Institute of Medicine. Workarounds significantly undermine an efficient point of care intervention designed to protect patients by ensuring the safe administration of medications, and creates opportunities for medication errors by nurses. An important step in addressing this significant problem is to identify barriers, or causes, that result in adaptations by nurses to circumvent BCMA. This step is vital in eliminating potential medication errors associated with workarounds and promote patient safety. The unnecessary harm and loss as a result of medication errors is unwarranted when there are tools available to reduce or eliminate these injuries. Identification of inadequate BCMA system designs will allow management to address solutions to increase the systems efficiency, which will secure nursing compliance, and ensure patient safety.

Literature Review:

The search was conducted through the search engines Google Scholar and PubMed by inserting the keywords “BCMA workarounds”, “medication errors with workarounds”, “workarounds with BCMA”, and “compliance with BCMA”. This produced 25 research articles dating back to 2006. Of these 18 papers were selected from the abstracts. Seven were used for the review on causes of BCMA workarounds and supporting the need for developing a quantitative tool for identifying common causes. A review of the literature produced definitions of the two concepts: 1) workarounds; defined as adaptations utilized by nurses to circumvent the BCMA system, and 2) causes that engendered workarounds, which were numerous. The causes were categorized under the four headings; 1) technology related, i.e. multiple scans needed, 2) task related, i.e. discarded packaging, 3) organization related, i.e. unreadable barcode, either med or patient, 4) environment related, i.e. location does not allow proper BCMA use.
Koppel, et al., (2008) conducted research, using Grounded Theory, to investigate what effect the BCMA had on medication errors, using five methods of data gathering: 1) structured observation, 2) unstructured observation, 3) structured interviews, 4) semi-structured interviews, and 5) sitting in on management meetings discussing overrides. Through direct observation the research team discovered that nurses were circumventing the BCMA system when they encountered a deficiency that caused a time/ task workflow barrier. This led Koppel, et al., (2008) to study causes of workarounds through interviewing nurses, and subsequently grouping the causes into four categories: technology, organization, human, and other/environmental. Koppel, et al., noted that there is a lack of research into the causes and effects of the workarounds. It was also noted that a quantitative tool needed to be developed in order to accurately assess the causes. The data collected would be the basis for the development of the necessary interventions for improved workflow design. These interventions would reduce workarounds and improve efficacy of the BCMA system.

Yang, et al., (2012) conducted a study in which the research design applies a theoretical perspective of accommodation and misfit, and workarounds with technology, to understand the phenomenon through an in-depth case study on workarounds. The research team noted that the system produced barriers for nurses that led to resistance by the users. When the system did not perform well and hindered the user the nurse circumvented the system. During the interviews several answers were given indicating barriers to complete utilization of the BCMA system. Yang, et al., (2012) expressed a lack of research concerning the causes of workarounds and the possible effect that the workaround has on medication administration errors. Yang, et al., suggests that research be conducted in these areas in order to increase the safety of the system for the
patients and increase compliance with the nurses. Additionally, quantitative tools to measure the
effects and causes of workarounds are indicated.

In their study on reworks and workarounds Halbesleben, et al., (2010) focuses on
medication administration with the BCMA in four hospitals ICU/CCU. A total of 58 nurses were
observed administering medication using the BCMA, followed with semi-structured interviews.
During the study the researchers observed that the workarounds were prominent within the
ICU/CCU and that it represents a serious safety concern. Failure to follow the BCMA protocol
interferes with the system’s ability to protect patients through ensuring the five rights.
Halbesleben, et al., (2010) notes that previous studies collected important data concerning the
support of the use of BCMA, however, there is little research to discover the causes of the
workarounds, or the medication errors associated with them. The understanding of workarounds
is an important area to collect data in order to preserve and advance the safety intervention of the
BCMA system.

Using a mixed-method systematic review to analyze technology used in medication
administration and the associated links to patient safety, Wulff, et al., (2011), concluded that most
of the research supports the increased safety associated with the technology. However, the
majority of the literature reviewed also indicated that nurses were using workarounds with the
BCMA system due to frustration in delayed workflow related to the design functions. This raises
concern due to the potential for medication administration errors from bypassing the safety
interventions the system is set up to perform. Yet, there is little literature that is focused solely on
studying the causes of the workarounds. Wulff, et al, (2011) states that “the scarcity of evidence is
linked to a lack of theoretically driven research design”, and researchers should be concerned with
developing “relevant theory and hypothesis” to produce stronger evidence-based research, which would drive management’s recommendations for improvement with the use of these systems.

Patterson, et al.’s, (2006) objective was to identify the “types and extent of workaround strategies with BCMA” within the hospital and long-term care settings. The study used an ethnographic approach using targeted observation in fifteen facilities. After analyzing the data, Patterson, et al., (2006) noted that several of the nurses were using bypasses to work around the BCMA system in order to accomplish their medication administration tasks within a timely manner. During the interviews nurses all expressed the belief that workarounds were necessary to perform efficiently, and that circumventing the BCMA system was more efficient than scanning the patient’s wrist band. Observed data corroborated the information obtained from the interviews. The nurses expressed that it was considered routine practice to perform these workaround strategies. The study by Patterson, et al., (2006) identified several types of workaround strategies with an accompanying cause as to the reason for the bypass. However, the causes are not categorized into any common occurrences, and the same holds true with the list of types of workaround strategies. The lack of categorization or quantification of the data prevents the study from identifying common causes that could be addressed by the management to intervene with improvements for increased compliance by the nursing staff.

Moyen, Camire, & Stelfox, (2008), performed a review on medication errors in critical care. This area was chosen for the high-risk patients and multiple medication intervention in a complex environment. The study notes that medication administration safety has improved; however, it is still high, especially in ICU/CCU. The use of technology to reduce medication administration errors has been instrumental in the reduction, but only when it is used according to the protocols set forth by the BCMA system. Yet, Moyen, Camire, & Stelfox, (2008) also noted
that the deficiencies of the system prompted nurses to create strategies to work around the system. The technology in place is adding to the potential for medication errors. The researchers believe that the healthcare industry should focus on developing systems that view humans as fallible, errors will occur, and remove the barriers that are impeding the compliance in using the BCMA system. Patient safety is an important issue and Moyen, Camire, & Stelfox, (2008), believe that “greater vigilance” through the development of assessment of the BCMA systems would benefit the integration of the technology within the healthcare industry.

Forni, Chu, & Fanikos, (2010) conducted a review of literature and concluded that technology is significantly important to reduce medication errors, especially in high risk areas, such as ICU/CCU. The literature review also emphasized that this technology was only efficient when utilized properly and with full compliance and that workarounds undermine the efficiency of the technology. Finally, Forni, Chu, & Fankos (2010) note that studies to evaluate the causes for noncompliance will add to the understanding of technology use and improvement.

**Gap in Literature:**

Research has focused on BCMA’s effectiveness as an intervention in reducing medication administration errors. A variety of studies also evaluated causes of workarounds when the phenomenon became apparent with the initial research. Data on the causes of workarounds was collected in conjunction with data on BCMA intervention of medication errors efficacy. These studies used grounded theory, direct observation and interviews to gather data, but the data was not quantified. A quantitative tool has not been developed, which could be used in future research. Few studies have focused on medication errors associated with workarounds. Several of the studies recognize a gap in research concerning the causes and the effects from workarounds and recommend that research be conducted to evaluate these two issues (Koppel, et al.,
Without a sound foundation based on quantitative analysis of causes it is difficult to understand the fundamental problems surrounding the BCMA system use by nurses. Understanding the bases of the workarounds through analytical evaluation of causes will assist in producing solutions to BCMA workarounds and validate the intention of implementing technology to reduce medication administration errors. Ensuring patient safety is always a priority and utilizing technology greatly reduces those risks. The gap in research this study will focus on is the lack of developed quantitative measurement tools that can be utilized in future research, especially by hospitals. Workarounds undermine the efficacy of the BCMA to perform as an intervention to prevent medication administration errors and reduce patient safety.

**Research Question:**

What is the correlation between BCMA barriers and workarounds among ICU nurses?

**Theoretical Model**

Eindhoven Classification Model was developed in Eindhoven, Switzerland, to be used for systematic analysis of root cause analysis studies involving safety events in industrial plants, and other high risk industries (van Vuuren, Shea, & van der Schaaf, 1997). The model builds on the belief that one incident is the result of a combination of multiple causation factors that lead to safety errors in three main categories, with a fourth category for “other”. The categories are as follows: 1.) organization factors, 2.) technical/task factors, 3.) human/individuals factors, and 4.) defenses/other factors, which are causes of failure that fall outside of the previous three categories; defense safety barriers, such as alarms or lights not functioning, patient dementia or other event (van Vuuren & van der Schaaf, 1997). The model places the initial investigation of root cause analysis in the categories preceding the human, or individual, factor, and moves sequentially into subsequent categories. Only after thorough analysis of the previous three
categories is the human/individual factor category examined. This is the last one addressed. Through thorough questioning at each stage all relevant information regarding an event are discovered. The conventional approach of an investigation of a medication error is to start with the individual, the nurse. However, the Eindhoven Classification Model reverses the thinking by shifting the analysis from focusing on the individual, to focusing first on the technology or organization side.

Eindhoven’s Classification Model will be used to develop a survey utilizing two categories: category one, organization, and category two, tasks/technology. The questions will be designed using data obtained from Table 2 “Probable Causes of BCMA Workarounds” from Koppel, et al’s 2008 study. Examples of survey question include: 1) organization related *i.e. new med order not in system*, 2) tasks/technology related *i.e. location does not allow appropriate BCMA use or battery failed*. 
Example of Classification Model of Latent Failures Causal Tree:¹


It represents the James Reasons Latent Failures Model, which is functionally equivalent to Eindhoven’s model. The Eindhoven model is in Appendix A.
**Variables of Interest:**

The two concept variables in this study are the workarounds and their causes. The workarounds that the nurses employ are concept variables that are dependent on the barriers/causes, and are defined in the literature as: adaptations or deviations in protocol with the BCMA system that allows the nurse to bypass the system in order to administer meds in a timely manner. The multiple barriers, or causes, that engender workarounds, such as patient wrist bands that are unscannable, are independent of the workarounds. The barriers/causes concept variables will be categorized into two groups: 1.) organization, 2.) task/technology. They will be measured using the Likert scale, an ordinal scale, which will be considered as an interval level of measurement for this study. The survey questions will indicate which barriers, as well as which workarounds, are most common. The results obtained will assist in developing solutions to the barriers and the outcome will be increased compliance in using the BCMA for patient safety.

Demographic variables are the characteristics of participants such as, gender, age, years of experience, F.T. or P.T, ethnicity, and level of education, and will be measured on the nominal level. The demographics will shed light on the nursing population that employs workaround tactics.

**Research Design**

The study is a descriptive correlation and will use a cross-sectional design. This is suited to the collection of data via a survey, which will be conducted at one point in time with each participant. There is no intervention or random groups for comparison. The focus of the survey are the variables of interest; 1.) barriers/causes of 2.) workarounds. The point in time is dependent on the participant’s availability. Direct observation or interviews will not be
conducted. The survey questions are to discover if there is an interrelationship between the variables. The survey will remain open for three weeks.

**Sample:**

Target population will be registered nurses (RN) working in ICU/CC who use BCMA, since the measurement tool will be utilized within the acute care setting in hospitals which use the BCMA. The method for obtaining the sample will be convenience, nonrandom sampling, chosen for convenience and based on voluntary participation, in order to meet the sample size needed.

The G-power was performed using the Test family as “exact”, the Statistical test+ correlation: Difference from constant (one sample case), Type of power analysis: A priori, Input parameters: Tails-one, Effect size r: 0.3, Alpha error probability: 0.10, Power (1-beta err prob.) 0.80, population correlation: 0. The Output parameters: Lower critical p: 0.186280, Upper critical p: 0.186280, Total sample size: 49, Actual Power; 0.801392.

The target sample size is 59 participants, based on the G-power Total n=49, and adding 10 additional participants to account for a potential loss of 20%. Power set at 0.80 and an alpha of 0.10 for a pilot study.

Other demographic variables of interest are: gender, age, years of experience, race/ethnicity, and level of education (Appendix B).

**Inclusion/Exclusion Criteria:** Inclusion criteria are ICU/CCU RNs, full time working at least 36 hours per week, or part time divided into two groups, those who work at least 24 hours per week and those who work less than 24 hours per week. Traveler RNs will be included since they are contracted to work at the hospital full time for several months, usually a year.

Exclusion criteria are RNs who do not work in the ICU/CCU, or registry RNs.

**Setting/Environment:**
The ICU environment is more autonomous with different patient needs and workloads, than other units in a hospital. The environment is complex involving constant distractions, frequent emergent events, multiple potentially lethal medications administered to each patient, as well as frequent medication changes both with the medications given or their dosages. The hospitals chosen are large, urban, general medical and surgical, hospitals.

Palomar Medical Center, a public district hospital with 368 beds and over 20,000 patient admissions in the past year, and employs 553 full time RNs and 220 part time RNs, in conjunction with their sister hospital, Pomerado Hospital, which is estimated to have half the beds and employees. Both hospitals have an ICU/CCU which has approximately 140 RNs total in these areas. The hospitals both serve a diverse patient population, including the Hispanic community and many of the under and non-insured populations.

Tri-City Medical Center is a large full-service acute care hospital with two advanced clinical institutes for cardiovascular and orthopedic care. The hospital has a 26 bed ICU/CCU that employs 67 RNs. This hospital serves a diverse population as well, including those within the Hispanic and other ethnic communities, as well as the under-insured.

**Measurement Tools:**

A review of the research and review literature reveals a lack of a developed quantitative instrument for measurement of barriers leading to workarounds that would be a useful tool for hospitals to evaluate the BCMA efficiency. The data collection method will be a self-report survey using a six point Likert scale. Concept variables, from Koppel et al. (2008), will be operationalized by selecting five questions from the categories under Table 2, “Probable Causes of BCMA Workarounds”, for a total of ten common causes correlated to workarounds. These will be posed as survey questions using the prompt “workaround” with answers agree/disagree, i.e.;
“Workaround occurs because of unscannable med” with the answer choices: 1) definitely agree, 2) agree, 3) somewhat agree, 4) somewhat disagree, 5) disagree, 6) definitely disagree (Appendix C). The categories of Organization and Tasks/Technology, were selected because they interface closely with workflow and patient safety, which the BCMA system is directly influencing.

The nurses use the BCMA to execute the task of medication administration, many times within a variety of situations, and are expected to do so within a time constraint. As such, it is important to identify specific points of failure within these two areas of organization and task/technical. The questions chosen appear to have a high frequency of occurrence. Should this be consistent with this survey, as well as larger surveys later, it suggests areas with the BCMA system that are common failings in which redesign may be indicated.

Answers will be quantified to determine level of occurrence with each of the ten causes. This will indicate which barriers within the two categories have the highest incidence of workarounds. The responses from the survey will also indicate which category, organizational, or task/technical, have a higher workaround response to barriers. The instrument will have face validity based on an assessment of the measurement tool by a cohort of RNs who are not participating in the study, and who have expertise from personal experience in this area of study. If statistically significant a post-hoc analysis will be conducted.

Because social desirability, defined as the “tendency to respond in a socially desirable manner to attitudinal questionnaires affects the validity of attitudinal questionnaires”, may be a factor in participant’s responses a Brief Social Desirability Scale (BSDS) short form survey of the Crown-Marlow Social Desirability Survey, will be conducted prior to the BCMA workarounds survey (Haghighat, 2007; Strahan & Gerbasi (1972). (Appendix D).
**Data Collection Process:**

The study and survey will be discussed at the ICU/CCU staff meeting. A recruitment e-mail explaining the study and survey will be sent out to all R.N.s in ICU/CCU twice over a two week period (Appendix E). Prior to the data collection, consent from the facility and informed consents from RN’s will be obtained. Data will be collected at one point in time with an end date of three weeks for completion of the survey submissions. Demographic information collected for additional information about participants for regression study to determine if characteristics have associations with variables. The characteristics are: gender, age group, hours worked per week, level of education, years worked, and ethnicity.

**Data Management:**

Determination of the secured survey system used at the institution will be obtained when meeting with management for approval of the study. SurveyMonkey will be the preferred management system. Anonymity of participant will be ensured by assignment of a number to each participant to increase confidentiality. Data access will be available to me, the chair, and committee member via secured user ID and password. Additional security to be utilized will be the public key infrastructure to manage a digital certificate access program, whereby each member is given a digital certificate that opens the files. SPSS will be used for storing and analysis of data.

**Data Coding and Scoring:**

Each of the two main categories, 1) organization related, and 2) task/technical related barriers (IV), will have five questions relating to one of the two categories of barriers, and will be coded: Organization-O1-O5, and Task/technical-T1-T5. Each answer is coded according to the six point Likert scale: 1) definitely agree, 2) agree, 3) somewhat agree, 4) somewhat disagree, 5)
disagree, and 6) definitely disagree. The coding will indicate the highest number of workarounds. Coding for demographic variables will be as follows: gender: 1) female 2) male 3) transgender; hours worked: 1) FT (36 hours or more per week), 2) PT (@ least 24 hours per week), 3) PT (less than 24 hours per week); ethnicity: 1) Hispanic, 2) non-Hispanic Black, 3) Asian, 4) non-Hispanic white/European; level of education: 1) ADN, 2) BSN, 3) >BSN, additional certification/specialty. Age and years of experience will be recorded in their numeric form. Missing values assigned 999.

Data Analysis:

Null hypothesis: There is no correlation between barriers in using the BCMA.

Alternative hypothesis: There is a correlation between barriers with BCMA.

For the analysis of data the level of measurement for each variable will be as follows: interval level for answers to survey questions concerning causes of workaround, and nominal for demographic variables, except for age and years of experience, which will be recorded in their numeric form.

Quantitative software program requirements are SPSS, an alpha level set at 0.10, for a pilot study, with a power set at 0.80. This pilot study will test the instrument and protocol before using them in a larger study on workarounds. “When the conventional significance level is P < 0.05, a pilot study might use a P-level of 0.10 or even 0.20. The purpose of the higher significance level in a pilot study is to avoid abandoning what might otherwise be a promising line of research on the basis of a pilot study that finds no effect for the treatment” (Windsor, Baranowski, Clark, & Cutter, 1994).
A scatter plot will determine the distribution of the variables, if normally distributed. Pearson’s correlational coefficient will be used to compute the strength of the relationships between the variables, if all of the assumptions are met.

Spearman Rho will be used for computing associations between variables as rank correlation coefficients. Internal consistency will be evaluated by calculating Cronbach’s alpha. Bonferroni correlation analysis will be performed for multiple correlation test.

**Limitations and Bias:**

The limitations of the design are that it is non-experimental, non-randomized, convenience sampling, at a single point in time due to time constraints. Because this is for development of an instrument and access is with one ICU/CCU of a single hospital, with a small size, 59 RNs, it may affect generalizability. Increasing the number of RNs involved in the sampling may reveal additional information that may be missed by using a smaller number of RNs for sampling.

The patient population and the work environment may be different in other hospitals. There may be additional causes for workarounds specific to different units, or other healthcare personnel outside of nursing. Other limitations may be: 1) instrumentation is reliant upon Likert Scale which restricts selection of answers to six and may not capture the full range of possible responses, 2) limited time for study, 3) unable to conduct direct observation with trained observers.

Potential bias related to study are: 1) recall bias related to effect of time between occurrences and time surveyed, 2) sampling technique reliant upon voluntary, nonrandom participation; possible cliques which may present a limited view through group think, or discussion of survey, 3) small sample size; may not represent broader views that could be represented with a larger sample size 4) investigator bias in developing questionnaire; practicing
RN or relationship through cohort identification-may bias choices of questions/answers, 5.) social desirability response set bias; giving responses that reflect desirable social views, 6.) extreme response bias; tendency to respond by choosing either “strongly agree” or “strongly disagree” that may distort data, 7.) acquiescence response bias; tendency to either always agree or disagree without regard to content of question.

**Threats to internal validity and control:**

The potential for recall bias related to the time between incidents occurring and time of recall with the survey. This will be controlled by limiting the event to within the past 60 days. Response bias is the tendency of the respondent to answer questions in a particular way regardless of the content of the question.

Midpoint response bias which is choosing the answer “neither agree/disagree”, will be controlled by using a six point Likert scale forcing a choice into one of the options in the agree or disagree range. Extreme response bias that gives results where most answers are “strongly agree/disagree” will be controlled by having an equal number of questions with a positive slant and a negative slant.

Temporal ambiguity, associated with an unclear understanding if the IV preceded DV, and vice versa, will be controlled with questions and answers that clarify the relationship, i.e. “Workaround occurred because of (cause)” with the ranges of agree/disagree answers.

Selection threat related to a nonrandomized sample is controlled through homogeneity. Homogeneity will control for internal validity as well as performing a post hoc analysis of variance. Additional bias may occur due to work association and familiarity with the respondents. This may result in social desirability response answers that are perceived to be desirable to the
surveyor. This will be controlled with the Crown-Marlow Social Desirability Survey, which will be conducted prior to the BCMA workarounds survey.

**Ethical Considerations:**

IRB issue will be addressed by securing an informed consent from each R.N. participant as well as consent from the facility where the survey will be conducted (Appendix F). Surveys will be conducted through a professional survey program, such as SurveyMonkey, to ensure anonymity and protect participants, thus ensuring confidentiality. Data access will only be available to research members who are given a secured password for access to the data.

Additional security to be utilized will be the public key infrastructure to manage a digital certificate access program, whereby each of the members is given a digital certificate that opens the files.
References


doi: 10.1097/CCM.0b013e3181f8569b

doi:10.2146/ajhp080355

doi:10.1097/NCN.ObO13e3181fc416d


Rivish, V., & Moneda, M. (2010). Medication administration pre and post BCMA at the VA


Eindhoven Classification Model - (medical version)
Appendix B

Demographics Survey: Circle the answers

Gender

1. Female  
2. Male  
3. Transgender

Hours Worked:

1. FT (36 hrs/more)  
2. PT (24 hrs)  
3. PT (<24 hrs.)

Race/Ethnicity

1. Hispanic  
2. Non-Hispanic Black  
3. Asian  
4. White/European

Level of Education

1. ADN  
2. BSN  
3. >BSN (cert./spec.)

Shift:

1. Day  
2. Night

Write in numeric form:

Age (in years): ____________

Years/Experience: ____________
Appendix C

BCMA Workarounds Survey Questions: Please answer the following by choosing 1 of the 6 answers. 1- Definitely agree to 6- Definitely disagree

Organizational:

Workarounds occur because:

1. *The medication is: only a different dose.*

   1) Definitely agree 2) Agree 3) Somewhat agree 4) Somewhat disagree 5) Disagree 6) Definitely disagree

2. *The medication order is not in the system.*

   1) Definitely agree 2) Agree 3) Somewhat agree 4) Somewhat disagree 5) Disagree 6) Definitely disagree

3. *The medication has a barcode is unscannable (wrinkled, torn, smudged).*

   1) Definitely agree 2) Agree 3) Somewhat agree 4) Somewhat disagree 5) Disagree 6) Definitely disagree

4. *The patient’s I.D. wrist band is unscannable.*

   1) Definitely agree 2) Agree 3) Somewhat agree 4) Somewhat disagree 5) Disagree 6) Definitely disagree

5. *BCMA scanning may slow for safe, timely delivery, i.e.: ER situations, pt. in isolation*

   1) Definitely agree 2) Agree 3) Somewhat agree 4) Somewhat disagree 5) Disagree 6) Definitely disagree
**Task:**

Workarounds occur because:

1.) *Battery dies; not charged.*

1) Definitely agree 2) Agree 3) Somewhat agree 4) Somewhat disagree 5) Disagree 6) Definitely disagree

2.) *Administration time preset, times out before meds administered.*

1) Definitely agree 2) Agree 3) Somewhat agree 4) Somewhat disagree 5) Disagree 6) Definitely disagree

3.) *Multiple scans needed.*

1) Definitely agree 2) Agree 3) Somewhat agree 4) Somewhat disagree 5) Disagree 6) Definitely disagree

4.) *Not typical barcode or missing.*

1) Definitely agree 2) Agree 3) Somewhat agree 4) Somewhat disagree 5) Disagree 6) Definitely disagree

5.) *Scanner failures.*

1) Definitely agree 2) Agree 3) Somewhat agree 4) Somewhat disagree 5) Disagree 6) Definitely disagree
Appendix D

Marlow Crowne Social Desirability Scale
Strahan & Gerbasi’s Short Forms of the Marlowe-Crowne Social Desirability Scale

True/False Items (number corresponding to the full MC scale listed)

Short Form M-C 2 (10)

2. I never hesitate to go out of my way to help someone in trouble.
4. I have never intensely disliked anyone.
6. I sometimes feel resentful when I don’t get my way.
12. There have been times when I felt like rebelling against people in authority even though I knew they were right.
14. I can remember “playing sick” to get out of something.
20. When I don’t know something I don’t at all mind admitting it.
21. I am always courteous, even to people who are disagreeable.
24. I would never think of letting someone else be punished for my wrong-doings.
28. There have times when I was quite jealous of the good fortune of others.
30. I am sometimes irritated by people who ask favors of me.

Reproduced from Strahan & Gerbasi, J Clin Psychol 1972;28:191-3 with permission from John Wiley & Sons, Inc. Copyright by John Wiley & Sons, Inc.
E-mail to be sent to all RNs in the ICU/CCU.

Hello,

I am working with Administration in [name of hospital] to conduct a survey within your ICU/CCU regarding the BCMA system. Participation is voluntary and anonymous; no one will know whether or not you participated. The informed consent is provided in the link below.

The survey is focused on possible barriers in the BCMA system that might force nursing staff to work around the system. The survey will be accessible on SurveyMonkey for 3 weeks.

As you probably know, BCMA barriers interfere with timely workflow and make medication errors more likely. We want to find ways to make the BCMA work better and get rid of the need for workarounds. The survey is a first step toward that goal. Here is a link to the survey:

[INSERT LINK HERE]

Participation is strictly voluntary, completely anonymous, and deeply appreciated.

Thank you,

Darshel Ontkean, RN, BSN, FNP student
Full review  x Expedited Review

Title of proposed project: Pilot Study: BCMA Barriers and Workarounds Among ICU/CCU Nurses

Check One: Faculty Research  x Student Research

Researcher Name: Darshel Ontkean  Date: 04-11-2015

Phone: 951-473-7381  E-mail: Ontke001@cougar.csusm.edu

College/Dept: Nursing  Check if in Joint Ed.D Program
(See special instructions in Item #10)

Faculty Sponsor

Faculty Sponsor Name: Dr. J. Daugherty

Faculty Phone: 760-750-7550  Faculty E-mail:jdaugherty@csusm.edu

Is this submission part of an external grant proposal? If Yes, SPAF #  x No

Faculty Verification on student research projects:

By submitting this form, you are verifying that you have reviewed this proposal for completeness and verified that it is in compliance with IRB regulations.

Submission Instructions

Electronic Submission –This document may be submitted by email to the IRB office by faculty only. Students must submit the document to their faculty sponsor for review. The faculty sponsor forwards the application to the IRB. Send to irb@csusm.edu.

- Word documents are preferred.
- The Consent Letter or Information sheet should be a separate Word document.
- CITI Training certification or an IRB Workshop certificate must be included.

Receipt via email from the faculty member’s email account will serve as their signature verifying that they have reviewed this proposal for completeness and that it is in compliance with IRB regulations.

Expedited reviews are reviewed by one committee member with an average approval time of approximately three weeks. Questions from reviewers and approval paperwork will be sent to the email address provided on the application at the time of submission.

Full reviews are reviewed by the full committee at an IRB meeting. Approvals on full reviews may take 4-6 weeks. Questions from the committee and approval paperwork will be sent to the email address provided on the application at the time of submission. All “full review” applications are copied to Risk Management.

If you have any questions, please refer to the IRB website or contact the IRB staff at (760)750-4029 or irb@csusm.edu.

NOTE: Completeness of this application will impact the timeliness of the review process.

Effective 8/1/2009, certification of training on Human Subjects Protection is required. To satisfy this requirement, a student may complete the CITI on-line training or attend the IRB workshop. Faculty must complete the CITI online training. Completion satisfies the training requirement for three years.
Summary of Research Protocol

Please answer each section completely and as succinctly as possible. Use lay terms as IRB members have diverse academic backgrounds. Please indicate N/A if the question does not apply to your research.

For assistance with completing this form, please review the following resources: [Video] [Samples]

1. Purpose of project and project background

Describe your research question, including why the question is important, and how your study will attempt to answer it. Include how your literature review supports this with at least three citations.

Statement of Problem: Although the healthcare industry has invested significant effort into decreasing medication administration errors by integrating the Bar Code Medication Administration (BCMA) scanning system into the hospital environment, nurses are creating workaround solutions to workflow barriers inherent within the BCMA system (Koppel, et al., 2008). This has undermined the efficacy of medication error intervention that the BCMA was designed to meet, and ultimately is a patient safety issue (Halbesleben, J.R.B., Savage, G.T., Wakefield, D.S., & Wakefield, B.J., 2010). Researchers have discovered the work around solutions used by nurses during their studies to determine the BCMA’s efficacy of reducing medication administration errors. Acknowledging the existence of deviations from the BCMA system safety program has been reported by several researchers, however, there is a gap in the literature that expresses that the next step in addressing the problem is to develop a tool measuring the barriers causing workarounds by nurses so that interface changes can be made in the BCMA system to ensure nursing compliance thereby ensuring the highest degree of patient safety (Forni, A., Chu, H. T., & Fanikos, J., 2010).

2. Recruitment procedures and participant population

a. Expected number of participants: 59 ICU/CCU RNs

b. Provide a profile of your proposed participant population including demographics. Explain why you are targeting this specific population.

Participants will be full time or part time RNs who work in ICU/CCU and use the BCMA for medication administration.

c. Indicate whether anyone might be excluded from participating and explain why.

RNs who are from a Temp. agency or who work outside of ICU/CCU. The temporary RN is not an employee and is usually not there for longer than a day. RNs outside of the ICU/CCU are not within the scope of the population that are being surveyed.

d. Please indicate whether any of your participants include people whose ability to give informed consent may be problematic (e.g., children, prisoners, mentally disabled, sub-ordinate or at-risk populations)?

The population recruited are educated, informed RNs. There are no issues concerning the inclusion of underrepresented or vulnerable groups or those who cannot give an informed consent.

e. How will you find, recruit, or identify potential subjects? How will you select, from the volunteers, the final group of participants? Will you be offering an incentive? If yes, please explain.

I will be meeting with the management of the ICU/CCUs in two different hospitals to gain approval for the survey. I will send an e-mail to all of the RNs employed by these hospitals in the ICU/CCUs to invite their participation with an explanation of the survey, the intent of the survey, the anonymity security, data security and that there is no consequence for not participating. There is no direct incentive to participate. However, the data will be useful in discovering barriers and solutions to the barriers of the BCMA system. This will enhance the use of the BCMA and secure patient safety which is an incentive in itself for nurses.

f. Will you be offering an incentive? If yes, please explain procedure for any incentives that will be offered. Include how much participants must do to be eligible to receive credit.

There is no direct incentive to participate. However, the data will be useful in discovering barriers and solutions to the barriers of the BCMA system. This will enhance the use of the BCMA and secure patient safety which is an incentive in itself for nurses.

g. Will you use recruitment flyers or other forms of media/communication to solicit participants? If yes, please explain and provide sample(s).

x Yes No
Explanation:

An e-mail that is approved by the management at the hospitals will be sent out to all of the RNs employed by these hospitals in the ICU/CCUs to invite their participation with an explanation of the survey, the intent of the survey, the anonymity security, data security and that there is no consequence for not participating. An informed consent form will be available through the e-mail.

Appendix E

E-mail to be sent to all RNs in the ICU/CCU.

Hello,

I am working with Administration in [name of hospital] to conduct a survey within your ICU/CCU regarding the BCMA system. Participation is voluntary and anonymous; no one will know whether or not you participated. The informed consent is included in the link below.

The survey is focused on possible barriers in the BCMA system that might force nursing staff to work around the system. The survey will be accessible on SurveyMonkey for 3 weeks.

As you probably know, BCMA barriers interfere with timely workflow and make medication errors more likely. We want to find ways to make the BCMA work better and get rid of the need for workarounds. The survey is a first step toward that goal. Here is a link to the survey:

[INSERT LINK HERE]

Participation is strictly voluntary, completely anonymous, and deeply appreciated.

Thank you,
Darshel Ontkean, RN, MSN-FNP student at CSUSM

3. Informed consent process.

- See web page on Informed Consent. See also Language Requirements.
- Provide responses for each population participating in your research

a. How and when will you explain the study and the required elements of Informed Consent? Will you be doing this or will it be handled by a research assistant?

I will be explaining the study and the element of informed consent at management meetings and will send it via e-mail to all of the participants.

Consent to Participate in Research

Darshel M. Ontkean, a student in the Master's of Science in Nursing-FNP program, at California State University, San Marcos (CSUSM), is conducting a pilot study survey that seeks to understand what causes ICU/CCU nurses to create

Study Objectives: The study is designed to answer the question: what are the barriers in using the BCMA which causes nurse to work around the system.

Procedures: This is a quantitative study that gathers data via a survey voluntarily participated in by ICU/CCU nurses. The questions will be posed as a potential barrier, ie. “Unscannable wrist band pt. identifier” with answers that are using point Likert scale with varying degrees of agree to disagree. The survey is voluntary, will be through SurveyMonkey, is completely anonymous, and will be open for 3 weeks.

Risks and Inconvenience: There is no risk anticipated in participating in the survey. It is completely voluntary and anonymity is secure. The survey will take approximately 10-15 minutes of your time. If you become fatigued or inconvenienced, you may stop at any time

Safeguards: The data collected does not include your name or any other identifier. It is completely anonymous, and is secured through SurveyMonkey. Only two individuals, myself and my chair, Dr. Daugherty, will have access to the data with a secured password.

Voluntary Participation: Your participation is completely voluntary. There is no consequence if you should decide that you do not want to participate.

Benefits: There is no direct benefit for you, except that you are providing essential information to address the BCMA system barriers that may yield important changes to the system to ensure increased patient safety as well creating a system that is user friendly for the nurses.

Questions: This study has been approved by the CSUSM Institutional Review Board (IRB). If you have any questions about the study, you may e-mail those to me, Darshel Ontkean, at ontke001.cougar.csusm.edu., or (951) 473-7381. Questions about your rights as a research participant should be directed to the IRB at irb@csusm.edu, or (760) 750-4029. You will be given a copy of this form to keep for your records.

This document has been approved by
The Institutional Review Board at
California State University San Marcos
b. How much time will participants have to consider between receipt of the informed consent document (or information sheet) and the beginning of study?
   3 weeks.

c. Are any subjects under age 18? If so, how will the study be explained to them? How will both parental consent and child assent be obtained?
   No subjects under the age of 18.

c. If you are requesting a Waiver of Signed Consent, explain why this waiver is needed. Outline alternative procedures for obtaining consent or providing study information (e.g., information sheet, introduction screen for web survey, telephone script).
   N/A

e. Indicate the primary language(s) of your participants. If any participants’ primary language is not English, and they are not fluent and comfortable reading English, explain how you will ensure that participants’ understanding of the activity for which they are giving consent.
   The primary language of the participants is English.

### 4. Procedures and Methodology — research protocol

- Provide responses for each population participating in your research

  a. Provide a step-by-step explanation of your research activities and methodologies. Explain how each activity contributes to the purpose of your research. Be thorough.

  *Sources of Data: A survey tool using Koppel’s Table of Categories of Barriers with the BCMA to determine the causes of workarounds, and using a six point Likert scale for the answers, will be the source of data acquisition. The participants are voluntary*

  b. State the specific dates/timeframe in which you plan to conduct your research.

    May 18, 2015 - Nov. 20, 2015

  c. State the location where the research will be conducted.

    Meetings with the hospital management will be conducted within each of the hospitals. The survey will be conducted on-line at the convenience of the participants. The data research analysis and writing will be conducted at CSUSM in an assigned office.

### 5. Participants’ debriefing or feedback

- If deception was involved in your research, participants should be debriefed about the nature of the study as soon as possible.

- All participants should be given the opportunity to request a copy of the results of the study/your final report.
6. Potential risks to the dignity, rights, health or welfare of the human participants.

- Please be sure the risks listed here
- Consider all risks very carefully. This is a critical area. For more information on risks, see Examples of Risk.
- Include any ‘inconveniences’ including the time requirement for participation.
- List risks for each population participating in the research and for each methodology.

a. List and explain potential risks to your participants. Risks may be both physical and psychological responses such as strong emotional and/or negative reactions to research questions.

There are no anticipated risks to human subjects, no confidential information collected, though the nurses who receive the email from their hospital will be informed of the nature and purpose of the survey, and may anonymously decline to participate. Subjects may become fatigued or feel inconvenienced by having to complete survey.

b. List risks related to confidentiality of data. What could happen if an unauthorized person accessed the data? For instance, participant’s identity or personal information could be known by others.

The data is secured through the SurveyMonkey site, as well as a password assigned to two members, myself and Dr. Daugherty, statistician, will secure information. The survey is anonymous, and voluntary, and does not require any identifying information from the participant.

7. Confidentiality and safeguards to minimize risks.

a. Please respond to each risk that you listed in #6 above. State how you will address each to minimize risks, protect confidentiality, and safeguard data.

b. In response to 6b, please indicate how you will safeguard data. Where/how will data be stored? Who will have access to the data? How will access be limited?

The data is stored and secured through the SurveyMonkey site, as well as a password assigned to two members, myself and Dr. Daugherty, statistician. This will secure information. The survey is anonymous, and voluntary, and does not require any identifying information from the participant.

If fatigued or inconvenienced by participation, subjects may withdraw at no penalty.

c. List referrals and/or resources that may be offered if a participant has a strong emotional response or a physical injury (e.g., clinics or shelters, medical or psychological referrals).

There are none needed for this survey.

8. Study benefits

Discuss any potential individual and/or societal benefits. Note, often there is no direct benefit for the participants but rather the study contributes to the literature and/or future research. If this is the case, please state this and explain. Be sure this aligns with the ‘purpose’ of this research.

There is no direct benefit for the participant, except that they are providing essential information to address the BCMA system barriers that may yield important changes to the system to ensure increased patient safety as well creating a system that is user friendly for the nurses.

b. Do the benefits from this study exceed the risks to participants? Please explain.

No

9. Researcher(s) qualifications and experience.

a. Briefly outline the primary researcher(s)’s qualifications and experiences relative to the subject of this research. Be thorough.

Darshel Ontkean is a BSN RN who has 4 years of experience in Medical/Surgical and PCU and 3 years of experience in ICU/CCU at a
large public district hospital. The BCMA system has been used by me in medication administration and I have directly observed my nursing cohorts utilize work arounds with the system to bypass barriers that impede the work flow and the administration of medications in a timely manner.

c. If this is a student project, include faculty sponsor’s qualifications.

Dr. Daugherty is the statistician for the project. Dr. Daugherty is a PhD, RN, CNL and faculty chair for the project

d. If using student assistants, include student(s)’ qualifications and training.

None used.

10. Checklist

Check which of the following items are included, as applicable:

Certification of Human Subjects Protection training for each researcher and the faculty advisor.

Recruitment flier(s) or advertisements, scripts for radio or TV.

Letter/email of organizational support (Required if recruiting or interacting with participants at a specific site or through a specific organization outside of CSUSM.) If sent in an email, must include organization and position person who approved.

Survey(s), questionnaires, or interview questions.

Consent and/or child assent form(s) or information sheet(s):

- Use an appropriate language level for your population
- Provide unique forms for each population in your research.
- Use official letterhead or the masthead found in the samples on the IRB website
- Include contact information!
  1. Researcher phone number and/or email,
  2. Faculty sponsor’s phone number and/or email address, and
  3. The IRB office (760-750-4029)
- Be sure the information in your consent/information sheet MATCH your application information!

IRB/Protection of Human Subjects

This is research on human subjects but exempt from IRB review.

*How the human subjects will be recruited and interacted with.* The research is a pilot study in which I will seek to obtain survey responses from 59 nurses at one hospital to a questionnaire provided through Survey Monkey. First I will present the proposed project in meetings with hospital administrators. If the administrators approve the project for their hospital, they will then send an email to all their Registered Nurses in ICU/CCU, containing a link to Survey Monkey and asking them to fill out the survey. Filling out the survey will be entirely voluntary. There will be no way for the hospital, myself, or anyone else to know whether a particular nurse filled out the survey or otherwise identify who filled it out and who did not, let alone find out what responses a nurse provided. I will collect no data that can be used to identify the individuals who answer the survey, nor any other identifiable private information.

*Research on human subjects.* This is a systematic investigation contributing to generalizable knowledge involving interaction with individual nurses, and therefore counts as research on human subjects.

*No underrepresented groups or vulnerable subjects.* Because I will be trying to obtain responses from a randomly selected group of 59 Registered Nurses, there will no issues concerning the inclusion of underrepresented groups in my human subjects. There are no vulnerable subjects.

*No conflict of interest.* I am the principal investigator. Dr. Daugherty is the statistician and methodologist. Neither investigator has any financial interest in the outcome of the survey, and no actual or potential conflict of interest.