Evaluating the Efficacy of Bar Code Medication Administration Use in an Emergency Department

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Abstract

Background: Safe medication administration through Bar Code Medication Administration (BCMA) had been widely supported in the literature, however, evidence on the efficacy of tethered versus non-tethered bar code scanners in the emergency department setting was lacking.

Objective: The purpose of this project was to evaluate the efficacy of medication scanning devices on patient scanning rates in an emergency department and to fully implement the most efficient technology.

Method: This was a quality improvement project using retrospective data from an existing database. Patient scanning rates for the emergency department were obtained in a retrospective manner.

Results: Patient scanning rates were found to be higher on tethered computers then non-tethered computers. There was no significant relationship to support either tethered or non-tethered BCMA scanners as it related to patient scanning compliance.

Conclusion: The recommendation from this study is to leave the current technology in place Given the results of this project, recommendations for the type of BCMA scanner should be based on cost of the product initially and rate of replacement. Further study should be conducted with a larger sample size in a more diverse clinical setting.

Keywords: Bar Code Medication Administration, medication errors, bar code scanning, medication administration, patient scanning

Evaluating the Efficacy of Bar Code Medication Administration Use in an Emergency

Background and Significance

Medication errors are among the most common errors committed in healthcare. Their effects translate into prolonged inpatient hospital stay, increased expenditures, and preventable in-hospital deaths (Anderson & Townsend, 2015). Since the publication of the Institute of Medicine (IOM) report *To Err is Human* in 1999, now known as the National Academy of Medicine, healthcare systems have instituted many changes in policies, procedures and practices that focus on increased patient safety and quality improvement. Today, there is additional motivation as hospitals can be deemed high-reliability organizations if they implement process improvement programs aligned with increased staff engagement that mitigate risk, including medication errors (Latney, 2016). A powerful strategy to reduce medication errors in healthcare systems is scanning of the patient and medication prior to administration using bar code medication administration (BCMA) technology. BCMA implementation can be remarkably effective in reducing medication administration errors. A study of BCMA-eMAR implementation in an academic medical center demonstrated a 41.1% relative reduction in non-timing errors in medication administration, resulting in a 50.8% relative reduction in potential adverse drug events (ADE) due to such errors (Poon et al., 2010). BCMA implementation in the emergency department has also shown a relative reduction of 80.7% in medication administration errors (Bonkowski et al., 2013).

Almost 20 years ago, the IOM (2004) published shocking data on preventable medication errors, reporting that 44,000 to 98,000 patients died each year, directly related to these preventable medication errors. These numbers are staggeringly high given the trained medical team providing care at the bedside. The IOM report noted that these errors were not due to the

poor practice of the individuals, but rather directly related to the design of the systems they followed, stressing that the processes in place should be designed to support the user, as humans will make mistakes. Yet, the number of medication errors associated with preventable deaths has changed very little (IOM, 2004; Early et al., 2011). New technological advances such as bar code medication administration systems and computerized physician order entry were developed to address part of the problem, specifically related to transcription errors and errors related to the five rights of medication administration. Bar code medication administration (BCMA) is a process where bar codes on medications being administered as well as bar codes on patient wrist bands are both scanned to verify the five rights of medication administration (the right patient, medication, dose, route and time), while computerized provider order entry (CPOE) ensures that medication orders are entered and transcribed correctly into the medical record by the provider. CPOE eliminates transcription errors from illegible handwritten orders. When both BCMA and CPOE are used together, medication errors that occur at the bedside can be prevented. These errors have been reported to occur 38% of the time (Lee, Lee, Kwon, & Yi, 2015). By utilizing a system that scans both the patient and the medication, discrepancies in the process may be easily identified. Discrepancies can occur at any stage of the BCMA process such as during medication preparation, patient and medication scanning, and matching and follow-up compromising the five rights of medication administration (Savage, Titus, Manns, & Lee, 2014).

In the emergency department (ED), the importance of utilizing the correct type of medication scanning technology is vital. To be used correctly, the technology must be designed to work within the complex and fast-paced, multiple patient environment, that the providers are faced with each day. Bonkowski et.al. (2014) noted that due to the nature of the ED, most direct error reporting looked at one-time, non-emergent medication administration events. Error rates in

these non-emergent administrations mostly saw an observed error related to the wrong dose. The focus of this project, therefore, is on evaluating the efficacy of two different types of medication scanning devices (tethered vs non-tethered) on medication administration errors in an ED environment in a 451 bed, not-for-profit community hospital in northeastern New Jersey.

Problem Statement

Lapses in patient scanning occur when the nurse manually enters the medical record number rather than scanning the patient barcode. Known as a work-around, this practice occurs for different reasons including missing or damaged barcode, technology failures, or poor compliance to policy (Rack, Dudjak, & Wolf, 2012). Medication administration systems should supplement the workflow and environment of the nurses when administering medications. Scanning of all patients with the BCMA system is the first step in safe medication administration at the bedside. When trained auditors shadowed nurses with a validated audit tool during the medication process, error rates are observed to drop by 54% after the use of a complete BCMA system (Rack et al., 2012). This demonstrates that proper use of the BCMA system reduces medication errors related to the five rights of medication administration.

While many barriers have been identified using BCMA, little has been focused on the type of technology used in the process. The purpose of this quality improvement project was to examine and compare the efficacy of two types of BCMA systems in the ED where the only BCMA system change was the switch from tethered bar code scanners to non-tethered bar code scanners. Tethered bar code scanners were scanners attached to a computer with a cable which has a limited length cable and must remain attached to the computer. Tethered scanners limit the range that a nurse can scan a patient from the computer due to length of the cable as well as physical barriers such as curtains, walls or medical equipment such as ventilators. Non-tethered

bar code scanners are those scanners that are not limited in their range to scan a patient from the computer by a cable or physical barriers such as walls, curtains or medical equipment such as ventilators. The compliance of each technology in patient scanning was assessed to identify the technology solution with the best outcomes for use in the fast-paced ED environment.

The PICO question that guided this project was: What is the relationship between tethered and non-tethered medication scanning devices used for patient scanning rates and nurse compliance with the scanning protocol in an emergency department?

Needs Assessment and Significance

Globally, evidence supports BCMA for the safe administration of medications along with other technologies in a streamlined complete administration system (Rack et al., 2012). Even with the proper electronic system in place, reported scanning compliance found in the literature approaches 100% but does not sustain at full compliance. This has been identified by the users for failures in technology, lack of resources, poor staff adherence to policy and human error (Lee et al., 2015).

The literature demonstrates that BCMA compliance rates are not where they should be due to the proven high risk of the event of medication administration. Richardson (2012) notes that typical published compliance rates for medication scanning ranged between 85% and 90% and Early, Riha, Martin, Lowdon, & Harvey (2011) reported an 82% medication scanning rate, with a near miss sentinel event, which triggered a safety concern and evaluation of the organization's BCMA rates.

National goals have not been set for scanning compliance by the government or other regulatory organizations. The Medicare Electronic Health Record Incentive Program, which is often referred to as "meaningful use," looks at different implementation and compliance rates for

other electronic health records metrics (HealthIT.gov, n.d.). These include use of CPOE and medication administration tracked on an electronic Medication Administration Record. Meaningful use has been a staged approach to compliance where scanning rates could be included in future stages of implementation.

There are no state regulated compliance goals for BCMA rates in New Jersey. Locally at the facility to be used in this project, a 451-bed not-for-profit community hospital in northeastern New Jersey with an emergency department that sees approximately 70,000 patients in its emergency department, reports an 86.66% patient scanning rate for 2016 in the emergency department with a goal of 95% compliance. This allows for an average of 13.34% of medication administration events for a medication error to occur, as the patient is not verified by bar code scanning.

Rack et al. (2012) and Richardson et al. (2012) note a 90% compliance rate is considered sufficient. However, this opens the door to the opportunity for errors 10% of the time. That 10% could result in a multitude of adverse medication events. Rack et al. (2012) quantified this for organizations with an estimated per medication error event cost of nearly $9,000 and an average increase in length of stay by 4.6 days. These numbers are significant when organizations are challenged to remain financially stable during the changes in insurance reimbursements. In the facility ED, with a 13.34% potential error rate over 70,000 patients per year, losses could equal several million dollars annually.

These financial cost projections and low compliance rates all demonstrate that the need is present for the project site to optimize BCMA to the fullest. One must only look at the compliance rate to see the areas of improvement that can be noted in the medication administration process. Noted at this project site are wide variations of medication administration

and adherence to policy are seen on units with different patient populations and varying technology. The emergency department captures all these patients except for laboring patients who are assessed in triage and bypass the emergency department and go to the labor and delivery unit directly. The unique ability to evaluate patient scanning rates for the diverse patients in the emergency department allows for a useful assessment of technology to be made. The project site looks to evaluate the further implementation of non-tethered scanners from tethered scanners currently used. An enhanced understanding of the rates of patient scanning is important as the cost of implementing and operating BCMA is a major investment for hospitals. A study by Sakowski and Ketchel (2013) estimated the cost of implementing and operating BCMA including electronic pharmacy management and drug repackaging over five years to be $35,600 to $54,600 per BCMA-enabled bed. As such, a 100-bed hospital can spend over $3 million in BCMA implementation over the initial five years.

Aims and Objectives

The aim of this project was to evaluate the efficacy of two different medication scanning devices on patient scanning rates and nurses' compliance with the scanning policy in an emergency department. Specifically, the objectives of this project were:

- Compare rates of patient verification (scanning) between tethered and non-tethered BCMA scanners in the emergency department;
- Identify which technology demonstrates a higher patient BCMA verification compliance;
- Determine the feasibility installing tethered vs non-tethered BCMA across the ED and other hospital units.

Review of Literature

When examining a health information technology recommendation, the IOM's six aims for the health system must be considered: safe, effective, patient-centered, timely, efficient, and equitable (Agency for Healthcare Research and Quality [AHRQ], 2016). When used appropriately, BCMA does not leave any room for discrepancies with the safety and quality of care provided to patients. It helps to remove errors when administering medications to patients with similar names and eliminates the 'human factors' element of mistakes as it pertains to drugs with similar names and packaging. This is important as barcode medication administration is intended to reduce the risk of medication errors in the administration process, which is where nearly 38% of preventable medication errors occur (Lee et al., 2015). By utilizing a system that scans both the patient and the medication, discrepancies in the process may be easily identified.

The medication administration process is a complex web of information, where patients and families first self-report their medication history in the stressful and unfamiliar environment of the hospital. From this accurate or inaccurate reporting, licensed independent practitioners then prescribe appropriate medications through a written or computerized system open to errors or interpretations by those entering the orders. The medications then dispensed by pharmacy could be exchanged due to hospital inventory, incorrectly labeled or other factors that reach the registered nurse and patient at the bedside. Here, if available, bar code medication administration (BCMA) is a final check before reaching the patient. While BCMA can identify errors in the medication administration system, it is only as effective as its rate of compliance. This process of prescribing and administering medications accounts for nearly 80% of the errors (Early et al., 2011). High-reliability organizations should encourage the use of BCMA within their practice to decrease health care expenditures, create more available bed space by reducing prolonged

admissions due to errors, and most importantly, save lives. When used properly, BCMA will help to reduce errors exponentially and improve the safety and quality of patient care.

Over ten years after the IOM report, Early et al. (2011) cites that these medication errors are still occur at an alarming rate. Error rates and patient harms vary by source as there is not a consistent reporting requirement for medication administration systems. Rack et al. (2012) notes that hospitalized patients are subjected to about one medication error per day, which increases the length of stay, cost morbidity and mortality. When discussing the statistics of mortality, it is reported that 7000 deaths continue to occur annually from these medication errors (Richardson et al., 2012). Makary and Daniel (2016) report a higher rate of medication errors that contribute to a quarter of a million deaths per year. Poon et al. (2010) notes that 25% of those reported errors are directly related to medication errors during the hospital stay. Death is not the only negative outcome related to medication errors. Documented mediation errors have been directly correlated to prolonged inpatient hospital visits and increased healthcare expenditures including ongoing healthcare costs (Anderson & Townsend, 2015). The need for a timely, electronic medical record and medication administration system is supported by Helmons, Wargel, and Daniels (2009) for improved patient safety and patient care, over paper documentation. These statistics demonstrate that even with technology such as BCMA, medication errors and medication administration remain a problem for hospitalized patients, families, facilities, and providers.

Having the correct technology in place to support BCMA is important to avoid nurse work arounds in the clinical setting. Miller, Fortier and Garrison (2011) note that even after BCMA systems are implemented, they need to be closely evaluated and monitored to support proper use to support safety. Workarounds observed by nurses during medication administration included omitted steps, which includes not scanning either the patient, medication, or both. It is

important to note that these data can often be obtained through reports within the BCMA system relating to override reports or other custom reporting metrics. This workaround was also observed by Koppell, Wetterneck, Telles and Karsh (2008) at a comparable hospital to size. These workarounds in similar sized organizations support that the appropriate technology must be in place.

Bonkowski et al. (2013) discusses an implementation of BCMA in the emergency department setting. This observational study demonstrated a significant reduction in medication administration errors, especially wrong dose errors, after the implementation of a BCMA system. This study did not look at the technology associated with the BCMA system. A gap in the literature exists when looking at tethered scanners and non-tethered scanners, specifically in the emergency department setting. Use and implementation supports both technologies, but no specific literature could be found on comparing the two technologies or to advise moving toward non-tethered scanning technology.

Theoretical Framework

Implementing and assessing changes in the changing healthcare environment requires a framework for guidance. In this project the Ottawa Model of Research was used, adapted from Graham and Logan 2004. This framework fit this DNP project well as it assesses a change process. The Ottawa Model of Research uses a six-step process. Step one was setting the stage. Understanding the impact of proper medication administration, following the five rights of medication administration, and understanding the financial and patient care impacts of failing to follow this process.

Step two looks at the innovation which was the two types of patient scanning technology, tethered versus non-tethered. While wireless technology has found its way into many technology

sectors, this does not demonstrate that wireless technology out performs tethered devices. With innovations in technology, the users are presented with new challenges such as battery power for wireless devices as well as misplacing the wireless technology since it is not physically connected to the computer.

Step three was retrospective as the event already occurred, focus will be on the evaluated difference between tethered and non-tethered. In step four, results from the existing database were analyzed retrospectively and an evaluation made as to whether the tethered or non-tethered scanner technology demonstrated a higher compliance rate of patient scanning.

Moving to step five and six were recommendations and process changes that can be incorporated into the remainder of the emergency department care areas.

Methodology

This was a quality improvement project to examine the rates of patient scanning in medication administration among users in an ED where a change was made in the BCMA system (tethered vs non-tethered). Data (patient scanning rates)were collected retrospectively using an existing database for an emergency department where bar code scanners were first tethered to computers by a 6-foot cord and then changed to a non-tethered scanner with a range of up to 50 feet. The purpose of this retrospective review project was to examine two different bar code scanner technologies to support a decision to implement the most effective technology throughout the areas of the emergency department. Effectiveness was based on patient scanning rates. The database used obtains data from the electronic health record used in the facility. Specifically, in this project, the data points related to location and if a patient was scanned using BCMA was accessed during a specific time. At least 1000 patient scanning events for each two-month period, defined as an RN scanning a patient, were extracted. No other data was used.

Setting

This project took place at a 451 bed, mid-sized, not for profit community hospital in northeastern New Jersey. The Emergency Department serves as a full-service ED, providing services in 41 patient rooms to about 70,000 patients annually. The department is staffed by board certified physicians, advanced practice providers, registered nurses and patient care associates. Patient acuity levels include treat and release patients to critical care hold patients. Medications covering these areas of care are provided on a regular basis, accounting for over two million medication administrations in 2017. Labor and delivery patients are not regularly seen in the department and if possible are brought directly to the labor and delivery unit for care.

Study Population

The study population was patient scanning rates from an emergency department obtained from an analytic database. Patient identifiers are not available in this database, data are only identified by unit. Additionally, while nurses are the ones conducting the patient scanning in this study, the nurse identifiers were not available in the database data extracted. Data were examined from March 1**,** 2017 to July 31, 2017. The first period dates evaluated were March 1, 2017 to April 30,2017. The second period dates were June 1, 2017 to July 31, 2017. May 2017 data will not be evaluated as this was the time period where one section of the ED was changed from tethered to non-tethered bar code scanners.

Exclusion criteria for this population was any scanning completed while the patient was in another location other than the unit being assessed (e.g., radiology) and any patients admitted who bypassed the ED, such as obstetrical patients. Patients are also not scanned during emergent events such as emergency respiratory or cardiac arrests; therefore, these were not included in the scanning numbers and do not influence the patient scanning compliance.

Study Intervention

The intervention that was evaluated in this project was the use of the tethered vs non-tethered scanners during the patient bar code scanning process of medication administration. This intervention is controlled in the database data, where the non-tethered scanners were installed over a week period from May 16, 2017 to May 23, 2017. Prior to May 16, 2017 all computers in this care area of the emergency department had the bar code scanners tethered to computers mounted on wall mounts in the patient rooms and on mobile computers in the department. After May 23, 2017, all bar code scanners were non-tethered on both stationary and mobile computers in this area. Data by computer or terminal number could not be obtained through the database. Following this investigation, implementation of the scanner with higher patient scanning rates was presented for implementation throughout the emergency department site.

Outcome Measures

The extracted patient scanning data percentages were extracted from the existing databased as the primary outcome measure. These data were during two, two-month periods in the same care area of the emergency department, which was important to note since it was segregated from the other areas of the emergency department. The first two-month period was prior to May 16, 2017, where the bar code scanners were all tethered to the computers. The first period dates evaluated were March 1, 2017 to April 30, 2017. The second two-month period was after May 23, 2017, where the bar code scanners were all non-tethered. The second period dates were June 1, 2017 to July 31, 2017.

Risks or Harms

This is a minimal risk, non-human subject study as this study was a retrospective database review, there was no risk of harm to a patient population or nursing staff during the project. Additionally, there was no protected health information accessed during this study. Only historical data on patient scanning rates was retrieved from the database for this study.

Subject Recruitment

Due to the design of this retrospective study from a database, no human subject recruitment was necessary.

Limitations

This project was limited by the use of a single site Emergency Department. Also limiting the study was the unavailability of medication error rates pre and post the installation of non-tethered BCMA systems as these data were prohibited for use by the project site Risk Management Department. Finally, The Information Systems department was unable to provide replacement cost data for either type of scanner during the time period of this study.

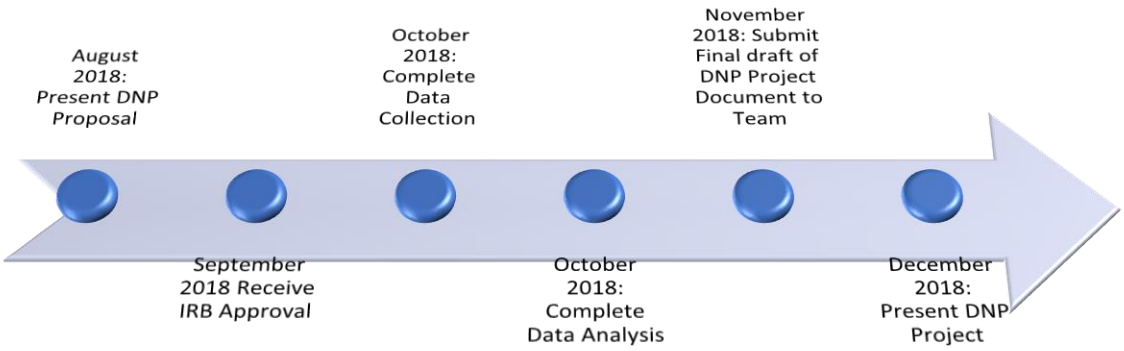
Consent Procedure

Due to the design of this retrospective study from a database, no consents were necessary.

Subject Costs and Compensation

Due to the design of this retrospective database review, there were no study participants to incur any costs or require any compensation. There were no participants in this study, only database review.

Project Timeline



Resources Needed/Economic Consideration

For this study there was no budget. No costs were incurred by this project, as previously recorded and available data was utilized.

Evaluation Plan

The data were collected, evaluated and disseminated to the audience of interest in the BCMA system optimal performance of scanner technology found in this emergency department setting.

Data Maintenance and Security

Only the project leader (PI) had access to specific data retrieved from the analytic software. These data were securely locked in a cabinet in the project leader's office during the time of the study, located at 223 North Van Dien Avenue, Ridgewood, NJ 07450, phone number 201-447-8193. This did include any electronic data, which was protected on a password

protected computer in a locked office. As required by Rutgers University, all aggregate data was kept on campus in Dr. Cheryl Holly's office (SSB 1125) on an encrypted device for the time specified by the Office of Information Technology.

Data Analysis

A chi-squared test was conducted to compare the means of the two data sets. The p-value set at 0.05 was then evaluated to see if there was a statistically significant difference allowing for the null hypothesis to be rejected, which it was not. A chi-squared test, (χ^2) is used to determine whether there was a significant difference between the expected frequencies and the observed frequencies in one or more categories. Following a determination of the most effective means of BCMA, a strategic plan was developed that addresses the steps below. Strategic planning is an organization's way of defining its strategy, or direction, and making decisions on allocating its resources to pursue this strategy.

1. Determine baseline and outcome data for comparison.
2. Identify priority issues
3. Describe what the anticipated outcomes of the plan will be
4. Determine accountability for training, implementation, budget
5. Plan for ongoing monitoring

Findings

After the scanning, compliance data were extracted from the analytics software at the study site and placed into the contingency grid below and a chi-squared test was conducted to compare the mean of the two data sets. With the p-value set at 0.05, no statistically significant difference as the chi square test was 0.88. Therefore, there was no statistical relationship noted with these findings to support either tethered or non-tethered BCMA scanners as it relates to patient scanning compliance.

	Tethered	Non-Tethered
Time frame 1	97.66%	96.80%
Time frame 2	97.35%	93.60%

χ^2 0.88; p>0.05,

As noted in the contingency grid above, the compliance rate decreased when the scanners were changed from tethered at 96.85% compliant of patient scanning, to non-tethered at 93.6% compliant. These rates were collected for patients in one section of the ED where patients did not move into other areas. The remainder of the ED had similar rates during both time periods at 97.66% in timeframe 1 and 97.35% in time frame 2.

Notably, although small, the compliance data extracted from the analytics database demonstrated a higher compliance of patient scanning with tethered scanners then with non-tethered scanners. There was a lack of support for either scanner in the literature however, further research would need to be conducted on a larger scale to support either technology.

The outcome in this study was to determine the feasibility of installing tethered vs non-tethered BCMA scanners across the entire ED. With the lack of statistically significant data to support either technology, the feasibility of department wide implementation based on patient scanning compliance is not possible.

Recommendations and Discussion

Economic and Cost Benefit

Given the nonsignificant findings in this project, recommendations for the type of BCMA scanner should be based on cost of the product initially and rate of replacement. The current tethered scanners in the ED cost $320, while the non-tethered scanners carry a cost of $624. The Information Systems department was unable to provide replacement cost data for either type of

scanner during the time period of this study, so cost of lost or damaged scanners was not able to be incorporated into the economic review.

As noted in the background, the ED contains 41 patient rooms. Of these rooms, 12 were in the segregated area and already outfitted with non-tethered scanners. To transition the remainder of rooms to non-tethered scanners would cost $18,096 (29 rooms x $624). To transition back to tethered scanners would cost $3,840 (12 rooms x $320). Without accounting for lost or broken scanners, information that could not be extracted from the site, the utilization of non-tethered scanners would have resulted in a cost savings for the organization of $14,256.

The recommendation from this study is to leave the current technology in place. Due to the reduced cost of the tethered scanners as each scanner needs replacement, the economic and cost benefit supports replacing all scanners with tethered scanners.

Impact on Healthcare Quality and Safety

This study found no statistically significant difference between the means of patient scanning compliance and scanning technology. As this relates to evaluating quality and safety, further research would be needed. This should be conducted with a larger sample size and after significant time has lapsed from implementation of the new technology to avoid possible non-compliance due to learning curves with utilization of the new technology.

National or state benchmarks for quality have not been established in this area of patient scanning compliance during BCMA. The opportunity to align quality and safety with BCMA through national benchmarks exists. Financial incentives for meeting these quality and safety metrics already exist by such bodies such as CMS and could encompass BCMA as well.

Policy Implications

As healthcare reimbursement is structured more in response to quality outcomes and patient safety, utilization of BCMA technology to prevent errors becomes more meaningful. As noted above, national benchmarks or goals for BCMA metrics have yet to be set. Until governing bodies prioritize the importance of BCMA metrics, organizations can continue to self-monitor and enforce policy on BCMA metrics.

Translation

As noted, no national benchmark had been established for patient scanning during the BCMA process. The site of this study had set the goal of 95% for patient scanning which will be the patient scanning goal for this technology to assist meeting or exceeding. The strategic plan for translation of this project is as follows:

Determine baseline and outcome data for comparison.

Current state is that each bed in the emergency department has one computer at the bedside, each with a tethered or non-tethered scanner. Of these computers at the bedside, 12 of the 41 already have non-tethered scanners. The final goal was to switch to non-tethered scanners for all computers, however, the data in this study did not support that change. Therefore, the new goal is for all 41 beds to have scanners that support meeting or exceeding the 95% target and being the most fiscally responsible with the technology available. The importance of this was that it was suspected that the non-tethered scanners have a higher patient scanning compliance rate. During this project it was noted that there was no statistically significant difference found between the two types of scanning technology.

Identify priority issues.

The priority issue remains meeting or exceeding the 95% target for patient scanning in the emergency department through use of the tethered scanners which adds an economical benefit to this implementation.

Describe what the anticipated outcomes of the plan will be.

To achieve the new goal of all 41 beds having the most cost-effective scanners and translation of the project into practice, purchase and installation of the tethered scanners should be performed as the non-tethered scanners no longer function and need to be replaced.

Determine accountability for training, implementation, budget.

Education with staff would not be extensive as the proposed technology is already in place in the department so staff are familiar with its use. Education would only be of informative updates to the staff as it relates to the findings of this study to support the economic benefits found. Implementation will need to be agreed upon by Information Systems and the Emergency Department for only replacement of tethered scanners moving forward. The budgetary implications will allow for reduced funds in the ED budget line for the replacement of scanners by 51% due to the cost of the scanners themselves. Emergency Department leadership will oversee this project with primary stakeholders being the directors of nursing informatics and information systems.

Plan for ongoing monitoring.

Stakeholders in these departments such as nursing directors, especially the director of nursing informatics, can utilize this or other studies to support the reduction of technological costs. Further monitoring and follow-up from ED leadership would be necessary to ensure patient scanning rates remained above the 95% goal. This would include both staff compliance

and technology maintenance. Further review of new literature to support patient safety in BCMA and increasing scanning compliance rates should be monitored and investigated to provide the safest, high-quality care in the ED.

Dissemination

The plan for disseminating this information back to the site will occur in three ways. First as required by the site research council, the findings related to the outcomes as well as this project will be shared with the site's Research Council as requested. Next, the study conclusions resulting in any nurse practice change will be shared with the Nurse Practice Council (NPC). The conclusions found resulting in a decreased patient scanning rate with the new technology implemented will be shared with the NPC. Finally, the findings of this study will be shared with the Emergency Department Leadership as well as the Information Systems department. Through disseminating the information with these two departments, specific action plans can be made in the future to maintain or improve quality metrics when new technology is implemented in this unique area of the hospital setting.

Professional Reporting

Sharing the results of this project with the larger professional community is of utmost importance to stimulate knowledge translation where it was lacking in the area of BCMA safety. Submission to a nursing informatics scholarly journal for publication and abstract submission for poster presentations at local and national conferences will also be conducted.

Publication allows for a formal and structured media searchable for those looking at this type of project. A manuscript has been drafted which will be finalized after this project is completed and submitted to Computers, Informatics, Nursing (CIN). This is a peer reviewed

journal which allows for open access to the published article, allowing readers globally access to this content. CIN has been a resource for nurses and clinicians for over 30 years. CIN's mission statement supports the professional reporting of this project's content and findings as it focuses on the implementation and management of health information technology within nursing and the healthcare setting (Computers, 2018).

Professional reporting at conferences allows for both presentation and interaction with other professionals to bring this project to clinicians and healthcare leaders. To achieve this, three conferences for healthcare leaders have been selected for abstract submission for poster presentations. They include the 2019 Organization of Nurse Leaders of New Jersey Research Day Conference, the 2019 American Nursing Informatics Association (ANIA) Annual Conference in Las Vegas, Nevada, and the New Jersey Council of Magnet Organizations, Inc. 2019 Research Conference. These conferences' timeframes allow this project to be submitted as poster abstracts to disseminate these findings.

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Appendix A

Rutgers University eIRB Approval

RUTGERS eIRB

DHHS Federal Wide Assurance Identifier: FWA00003913
IRB Chair Person: Cheryl Kennedy
IRB Director: Carlotta Rodriguez
Effective Date: 11/14/2018

eIRB Notice of IRB Determination

STUDY PROFILE

Study ID: Pro2018002239
Title: Evaluating the Efficacy of Bar Code Medication Administration use in an Emergency Department

Principal Investigator:	Derrick Lieb	**Study Coordinator:**	Derrick Lieb
Co-Investigator(s):	Cheryl Holly Tracy Vitale		
Review Type:	Non-Human Determination		

CURRENT SUBMISSION STATUS

Submission Type:	Request for Determination of Non-Human Subject Research (including Quality Assurance/Quality Improvement)	**Submission Status:**	Approved
Determination Date:	11/12/2018		

Site IRB Approval

October 25, 2018

Derrick Lieb
[redacted]

Dear Mr. Lieb:

SUBJECT: REGULATORY OPINION: IRB EXEMPTION

Protocol Title: Evaluating the Efficacy of Bar Code Medication Administration Use in an Emergency Department
PI: Derrick Lieb

This letter is in response to your request for an opinion as to whether the above mentioned project would constitute human subject research requiring IRB review.

This opinion is based on federal regulation 45 CFR 46 and associated guidance.

Under 45 CFR 46.102(d), research means "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes…."

The Office of Human Research Protection has issued guidance indicating that quality improvement projects do not meet the definition of research. This guidance states:

Question 2: Do the HHS regulations for the protection of human subjects in research (45 CFR part 46) apply to quality improvement activities conducted by one or more institutions whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes?

Answer: No. Such activities do not satisfy the definition of "research" under 45 CFR 46.102(d), which is "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge…" Therefore the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

This project does not involve research. This project uses retrospective data from an existing database to measure medication scanning rates from two types of bar code scanners used by an emergency room (tethered versus non-tethered or wireless) in order to measure efficacy of the two systems and then implement the most efficient technology in the future. Therefore, WIRB has determined this project is not research and does not require IRB review.

This determination that this project is not research subject to 45 CFR 46 can apply to multiple sites, but it does not apply to any institution that has an institutional policy of requiring an entity other than WIRB (such as an internal IRB) to make such determinations. WIRB cannot provide a determination that overrides the jurisdiction of a local IRB or other institutional mechanism for making such determinations. You are responsible for ensuring that each site to which this determination applies can and will accept WIRB's determination.

Please note that any future changes to the project may affect its status as research, and you may want to contact WIRB about the effect these changes may have on the status before implementing them. WIRB does not impose an expiration date on its determinations of research.

If you have any questions, or if we can be of further assistance, please contact Bridget D. Brave, JD, at 360-252-2466, or e-mail regulatoryaffairs@wirb.com.

BDB:dj

Not Research-Quality Improvement Exemption-Lieb (10-25-2018)

cc: Sequoia L. Young, [redacted]

WIRB Accounting

WIRB Work Order #1-1125216-1

Appendix B

Data Collection Tool for Bar code medication scanning in an Emergency Room

User	Date Range	Total number of patients documented who received medication	Number of patients scanned for these medication administrations	Percent Compliant (Number of patients scanned for these medications administrations/Total number of patients documented who received medications)
1	3/1/17 to 4/30/17	19,032	18,586	97.66%
2	6/1/17 to 7/31/17	19,110	18,604	97.35%
3	3/1/17 to 4/30/17	1,625	1,573	96.80%
4	6/1/17 to 7/31/17	1,672	1,565	96.30%