Improving Medication Labeling Compliance in the Wright-Patterson Medical Center Operating Room Amongst Anesthesia Providers

Kelli Gruss, H. Tammy Huynh, and Shannon Nunnery

Daniel K. Inouye Graduate School of Nursing

Uniformed Services University

Wright-Patterson Medical Center

April 15, 2023

Distribution Statement

Distribution A: Public Release.

The views presented here are those of the author and are not to be construed as official or reflecting the views of the Uniformed Services University of the Health Sciences, the Department of Defense or the U.S. Government.

Copyright Acknowledgement Statement

The authors hereby certify that the use of any original work by another author or copyrighted material used in the DNP project entitled: "Improving medication labeling compliance in military treatment facility operating rooms amongst anesthesia providers," is either appropriately cited within the manuscript or used with formal written permission of copyright release by the owner of the original work.

GRUSS.KELLI.D.1364299555
Digitally signed by GRUSS.KELLI.D.1364299555
Date: 2023.04.11 08:58:21 -04'00'

Maj Kelli Gruss
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University

HUYNH.HAI.PHUONG.T.1385168132
Digitally signed by HUYNH.HAI.PHUONG.T.1385168132
Date: 2023.04.11 08:50:44 -04'00'

Maj H. Tammy Huynh
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University

NUNNERY.SHANNON.1162321192
Digitally signed by NUNNERY.SHANNON.1162321192
Date: 2023.04.11 10:48:05 -04'00'

Capt Shannon Nunnery
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University

Table of Contents

Disclaimer

The views expressed in this report are those of the authors and do not necessarily reflect the official policy or position of the Uniformed Services University, Wright-Patterson Medical Center, the Department of Defense, Department of the Air Force, Defense Health Agency, or the United States Government. There are no financial relationships that exist between the speakers and a commercial entity.

ABSTRACT

Phase II Site: Wright-Patterson Medical Center (WPMC), Dayton, Ohio

Project Title: Improving Medication Labeling Compliance in the Wright-Patterson Medical Center Operating Room Amongst Anesthesia Providers

Authors: Kelli Gruss, H. Tammy Huynh, and Shannon Nunnery

Background: An estimated 180,000 patients die annually from adverse medical events and a significant cause is medication errors. Adverse events from medication errors in anesthesia are second only to airway-associated events. These errors can lead to minor or major harm, patient awareness, or death. Literature shows medication labeling compliance rates of only 36%, despite the high-risk nature of many medications.

Clinical Question: Among anesthesia providers at Wright-Patterson Medical Center, how does the implementation of a multifaceted intervention compared to standard practice affect compliance with medication labeling standards?

Project Design: This was a quality improvement project divided into five phases. Phase 1 consisted of performing a baseline audit of disposed labeled syringes. Phase 2 involved a baseline knowledge assessment of The Joint Commission (TJC) standards for medication labeling. Phase 3 included implementation of customized pre-printed labels and staff education on TJC medication labeling standards. Phase 4 consisted of a repeat audit as in phase 1. Phase 5 consisted of a repeat staff knowledge assessment and inquiry of likelihood of practice change. The post-intervention data collected was compared to phase 1 and phase 2, respectively, to demonstrate quality improvement.

Analysis of the Results: The EBP team utilized the paired t-test to evaluate the outcomes.

Organizational Impact: Evaluation of medication labeling practices before and after the intervention determined that medication labeling compliance was improved through a multifaceted intervention. Improved medication syringe labeling compliance may decrease medication errors, improve patient safety and reduce medication waste, however our project focused solely on provider labeling practices. These actions coincided with the Defense Health Agency's (DHA) Quadruple Aim initiative and aligned with the DHA's Strategy FY21 Campaign Plan. Based on the results, we determined our intervention made a meaningful impact on staff labeling compliance.

Improving Medication Labeling Compliance in the Wright-Patterson Medical Center Operating Room Amongst Anesthesia Providers

Patient safety is one of the most important aspects of patient care, yet medical errors still frequently occur resulting in patient harm. Medication errors are one of the leading causes of sentinel events despite protocols and guidelines meant to reduce the frequency. Improper labeling and administration of the wrong drug or dosage have caused the majority of critical incidents (Nanji et al., 2016). Medication labeling standards set forth by accreditation organizations such as The Joint Commission (TJC) have been established to minimize these errors and military treatment facilities (MTFs) are required to meet the standards they set. At WPMC, the number of perioperative anesthetic-related medication labeling errors was difficult to assess. Patient safety reports from these incidents were lacking; however, multiple safety reports were made by the facility's pharmacy department due to negligent medication handling. This included improper storage of medications, medications without proper labeling, and medications being used past their expiration date. Despite being aware of medication handling policies, complacency from the staff and burdensome medication labels contributed to these incident reports. Additionally, the policy needed strict reinforcement from leadership for staff compliance. Medication labeling practices within WPMC's anesthesia department may need revision through a multifaceted intervention to reduce the possibility of medication errors, improve patient safety, and comply with accreditation standards.

Problem Synthesis

An estimated 180,000 patients die annually from adverse medical events, and a significant cause is medication errors (Prabhakar et al., 2015). Adverse events from medication

errors in anesthesia are second only to airway-associated events (Prabhakar et al., 2015). These errors can lead to minor or major harm, patient awareness, or death. A systematic literature review of 98 relevant references by Jensen et al. (2004) states that 100% of studies acknowledged "syringes should be labeled (always or almost always)" (p. 497). TJC (2021) has recognized the importance of medication labeling on patient safety and set criteria under National Patient Safety Goal 03.04.01 and Medication Management 05.01.09 for drug labels, including medication name, strength, expiration date and time, time prepared, preparer's initials, amount of medication or solution (if applicable) and diluent name and volume (if applicable) for all medications prepared in advance. Anesthesia providers prepare up to 20 medications in advance, and this preparation commands a significant amount of the providers' preoperative and intraoperative time (Fraind et al., 2002). Medication-related tasks consume 20-30% of anesthesia providers' intraoperative time, 50% of standard pre-case preparation and up to 75% for cardiac cases (Fraind et al., 2002). It is understandable that handwritten medication labels may not meet all TJC requirements. Jelacic et al. (2015) showed anesthesia providers' medication labeling compliance rates at only 36% despite the high-risk nature of many of our medications.

Additionally, anesthesia providers have no systemic safety checks in place; prescribing, obtaining, preparing and administering medications are carried out by a single provider. One study surveyed 687 anesthesiologists, revealing 85% of participants had experienced at least one drug error or "near-miss" (Orser et al., 2001). Previous studies relied on provider self-reports, estimating a medication error rate of 1 in 133, but an observational study by Nanji et al. (2016) found that a medication error or adverse drug event occurred in approximately 1 of 20 medication administrations and half of all surgeries. A literature review by Bekes et al. (2021)

reported that 70% of perioperative medication errors involved incorrect dosing and 35% were wrong drug administration. Accurate and complete medication labels for drugs prepared in advance reduce the patients' risk of wrong drug or dose administration.

According to Fraind et al. (2002), hand-written labels are often difficult to read and wear off, and many providers experience difficulty tearing off pre-made standardized labels from the rolls. The benefits of improving this process are increased compliance with the safety standards as well as reduced costs by mitigating the risk of malpractice claims. WPMC's anesthesia department lacked an evidence-based approach to minimize the occurrence of medical errors caused by incomplete medication labeling and thus could improve patient safety, decrease time away from patient care, and increase compliance by updating their medication labeling process. This, along with an increase in occurrence of pharmacy inspection failures, led the leadership within the anesthesia department to request an evidence-based approach to mitigating this risk.

Relevance to Military Nursing

MTFs are the linchpin for military medicine in supporting operational units (Military Health System [MHS], n.d.). The Defense Health Agency (DHA) utilizes the Quadruple Aim Performance Process standardizing performance across the MHS for quality care (DHA, 2019). This strategy integrates health care delivery and readiness, creating a foundation for the Combat Support Agency's mission. As part of the Quadruple Aim, improved readiness is at the center of better health, better care, and lower cost. A total military force is dependent on quality care, eliminating waste, and reducing generators of ill health. To assess the quality of care, MTFs are accredited by nationally recognized organizations such as TJC, which have stringent criteria for quality patient care. Despite efforts to thwart medication errors, medication safety remains a top

focus for the MHS (MHS Review Group, 2014) citing medication errors as one of the top five causes of process improvement investigations.

In addition to the Quadruple Aim, the DHA Strategy also includes the FY21 Campaign Plan, which is an operational approach to execute four priorities: great outcomes, a ready medical force, satisfied patients, and fulfilled staff (DHA, 2021). Improved patient safety, including medication error reduction, is the centermost of these four priorities. Regardless of the mission and objectives, the DHA's strategic goal is to provide and maintain a healthy military force which will be met through compliance with TJC standards. Wright-Patterson Medical Center is the second largest MTF and provider of surgical care in the Air Force with 3,400 surgical procedures performed annually.

Clinical Question

We performed our literature search based on the PICO question: Among anesthesia providers at Wright-Patterson Medical Center, how does the implementation of a multifaceted intervention compared to standard practice affect compliance with medication labeling standards?

Search Strategy/Results

Utilizing this question, we searched PubMed and CINAHL databases using the keywords anesthesia, anesthetic, perioperative, medication administration, drug administration, drug safety, Codonics, medication error, barcode scanning, barcode scanner, barcode scan, safe label system, safe labeling system, electronic audit, provider compliance, compliance, TJC, and The Joint Commission. We excluded articles that included the Federal Drug Administration or Food and Drug Administration, limited our search from 2011 to 2021 for a 10-year span, and limited to

peer-reviewed articles in CINAHL. We also utilized hand-searching in Google Scholar which brought in one additional article. We received 853 results once duplicates were removed, 795 were irrelevant to our problem and 58 were reviewed in full text by one of our three team members. Of those 58 articles, 53 were excluded for various reasons (23 no drug labeling relevance, 13 wrong study design, eight wrong outcomes, three full texts not available, one each for color-coding specific, no electronic labeling relevance, not in English, wrong intervention, wrong patient population, and wrong subject population). Our PRISMA flow diagram is shown as Figure A1 in Appendix A. The retained articles were evaluated with the Johns Hopkins Appraisal Tool with levels of evidence ranging from I-III (one level I, three level II, and one level III). All articles were appraised at B or good quality and are summarized in Appendix B.

We conducted a separate search to determine the most effective interventions to improve medication labeling compliance behaviors. We determined that hand hygiene was a more studied task that is analogous to medication labeling as healthcare providers know it is important, but are not always consistent in performing. We searched PubMed using the terms healthcare workers, behavior change, hand washing, and intervention or theory. Filters were applied for English language, published between 2011 and 2021 for a 10-year span, and full text available. This search generated 62 articles, 48 were screened as irrelevant, and 14 were reviewed in full text by at least one member of our team. Of those 14 articles, eight were excluded for wrong intervention, two for wrong study design, and one for wrong outcome. The PRISMA flow diagram is included as Figure A2 in Appendix A. The three retained articles were evaluated with the Johns Hopkins Appraisal Tool with one of each categorized as level of evidence IB, IIA, and IIIA. These studies are summarized in the evidence table in Appendix B.

Solution Synthesis

Our literature review clearly outlined the problem of medication errors in anesthesia, with accurate syringe labeling as a cornerstone of wrong drug or wrong dose prevention. In the studies reviewed, the consensus is that the optimal label will be legible, water resistant, save clinician time, contain a barcode for electronic health record (EHR) integration, contain TJC-compliant labels that meet American Society of Anesthesiologists (ASA) and International Organization for Standardization (ISO) guidelines, and maintain continuity of medication from original vial to administering syringe. The ASA (2020) recommends syringes include most prominently the generic drug name and concentration in units per milliliter, as well as the date and time of preparation, and the preparer's name or initials. The ISO anaesthetic labeling guidelines set a standardized color for each medication classification. For example, fluorescent red is used for muscle relaxants and yellow for induction agents (Australian Commission on Safety and Quality in Healthcare, 2015). Color-coding may help to quickly determine drug class but does not differentiate between drugs of the same class or different concentrations of drugs, and does not account for difficulties such as color blindness or low visibility working conditions.

There have been multiple studies that piloted ways to standardize and improve labeling processes. One of them used pre-printed ISO standard labels which are typically available in rolls using plastic dispensers. This is convenient and economical, but due to multiple sizes necessary for both fluid bags and syringes, a large number may be required, and a concerted effort is necessary to ensure the dispensers are kept clean and do not develop into fomites (Merry et al., 2011a). In a study by Fraind et al. (2002), clinicians were frequently observed experiencing difficulty removing these pre-printed labels from the dispenser above the anesthesia

cart. The providers showed frequent frustration in performing this task, and several reported cutting their knuckles on the label dispenser. These labels also have limited space so the preparer is constrained in how much information can be included. Commonly, neither pre-printed rolls or sheets are fluid resistant, and the time requirement and legibility of provider-written information is not addressed.

An entire anesthesia workstation system is available, known as the SAFERSleep System. This is a multimodal intervention incorporating systematically organized medication drawers, pre-filled syringes of commonly used anesthetic drugs, a barcode scanning system connected to speakers and a monitor, and is incorporated into the anesthesia charting system. An observational study by Merry et al. (2011b) showed a lower medication error rate with this system (1 in 625 administrations) compared to the conventional system (1 in 303 administrations). The study compared this system against conventional handwritten record keeping systems, so it may not be applicable to WPMC. There was, however, overall provider preference for the system which may indicate components that could be transferred into WPMC, such as pre-filled syringes of drugs commonly used in anesthesia. A literature review of perioperative medication errors showed pre-filled syringes are effective in reducing medication errors and were utilized in 53% of studies reviewed (Bekes et al., 2021). Pre-filled syringes reduce provider preparation time, are prepared in commonly used concentrations, and have a significantly longer shelf life than provider-prepared syringes.

The interventions above only partially meet the optimal criteria. The Codonics Safe Label System (SLS), is a point-of-care labeling machine used in over 700 hospitals worldwide including the Department of Veterans Affairs and 25 MTFs (Codonics Patient Safety, 2021).

Jelacic et al. (2015) describes the function and customizability of this FDA approved machine:

> It scans the drug vial barcode and generates a compliant color-coded syringe label that is adaptable to the recommendations of regulatory agencies and standards-setting bodies. The user can modify the syringe label contents to generate a label that is compliant with any labeling standards. (p. 410)

Once the original vial is scanned, the machine reads aloud the drug name and concentration. An audible confirmation prior to drug preparation may reduce the chance of the wrong medication being drawn up or administered. While the label is being generated, the clinician can prepare their medication syringe, saving them valuable time. Once the label is affixed, the user can then scan the label into their EHR (if equipped to do so) for administration charting. As of this writing, several commercial anesthesia information management systems (AIMS) are capable of scanning syringe label barcodes. However, none of the currently available AIMS feature the robust capability of providing continuity between scanning the original vial barcode and generating a corresponding syringe barcode label in the operating room. In the Jelacic et al. (2015) study, the use of the Codonics SLS resulted in over 75% compliant syringe labels; only those labels made by providers were deficient. In a separate study by Thomas et al. (2020), 100% of the 669 syringes received a label with all required information in their post-implementation audit. Several studies showed that respondents believed the Codonics SLS system was easy to use, accurate, met their needs, printed labels quickly, improved safety and efficiency, and was recommendable.

Despite the benefits of the Codonics SLS and SAFERSleep systems, there may be barriers that prevent the utilization of this technology, most notably the significant cost

associated with purchasing the required equipment. The anesthesia department at WPMC requested purchase of the Codonics SLS but were denied sufficient funds to implement in the operating rooms. In that situation, an analysis and implementation of behavior modification interventions may improve provider compliance. Huis et al. (2012) discuss a strategy derived from behavior change theories addressing various determinants of behavior change. These determinants were categorized into nine areas: knowledge, awareness, social influence, attitude, self-efficacy, intention, action control, maintenance, and facilitation (de Bruin et al., 2009, as cited in Huis et al., 2012). A review of 41 studies showed the relative difference in compliance correlated with the number of determinants of change addressed (Huis et al., 2012). Utilizing two, three, four, and five determinants had, respectively, 25.7%, 42.3%, 43.9% and 49.5% relative increases in compliance (Huis et al., 2012). Additionally, Huis et al. (2013) found that the determinants of leadership and social influence were positively correlated with increased compliance rates. Using a combination of these determinants to improve labeling compliance may result in a more effective behavioral and cultural change compared to using a sole determinant.

Focus Areas

Modification of providers' behaviors through multifaceted intervention may improve compliance. In order to meet this goal, four behavioral determinants were addressed: knowledge with general information, awareness with risk communication, self-efficacy with guided practice, and facilitation of behavior by providing customized pre-printed medication stickers with prompts for a minimal amount of required information. The customized pre-printed medication stickers met several needs: consistently comply with TJC medication labeling requirements, be

easily incorporated into anesthesia providers' workflow with simple instructions to use, and not increase the time required to prepare medications.

Business Case Analysis

Our business case analysis (Appendix C) outlines three viable options to improve medication labeling compliance among anesthesia providers at our facility and their cost-benefit analysis.

The first option was to purchase the Codonics SLS for each of the 10 operating rooms at our facility. There is an initial investment in the system and staff adjustment to a slight change in workflow, but this option adds an audible medication confirmation in addition to fully compliant labels for each medication prepared. With the added safety features of this system, this option creates an estimated $1,773,075 in savings, primarily through averted litigation. Adding new systems to the operating room requires authorization beyond our local administration, which prevented the implementation of this intervention.

The second option was to utilize pre-filled syringes for commonly used medications - especially emergency or high risk medications such as vasopressors and paralytics. This option reduces provider workload, ensures consistent preparation and concentration, and may prevent medication waste from medications being prepared but not used. A significant concern with this plan is that pre-filled syringes from manufacturers are at risk of supply chain shortages and did not solve the problem for all the medications used by anesthesia providers.

The third option was to provide the anesthesia providers with education on TJC medication labeling requirements, risks of improperly labeled medications, and provide customized pre-printed labels daily. Providers may not have had knowledge of what is required

on a medication label and compliance could be improved through education and fostering of a patient safety culture. This plan was low cost and decreased provider time spent labeling by minimizing the information providers were required to place on the labels. It required reinforcement to maintain staff vigilance and become ingrained into the workplace culture, and placed additional workload on the anesthesia technicians who printed label sheets daily. Reinforcement was provided by posting a visual reminder of labeling requirements on anesthesia medication carts in each operating room and customized labels provided daily on those carts.

After comparing the pro/con analysis for each of the proposed plans, option three was the best course of action to increase medication labeling compliance amongst anesthesia providers. Increasing provider knowledge and awareness combined with provision of customized labels may reduce provider workload while providing a consistent, sustainable, and low cost solution to improperly labeled medications.

Organizing Framework

We utilized the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) model as a reliable tool for translation of our research into bedside practice (RE-AIM, 2021). This framework has been widely applied to assess the impact of individual interventions, especially when applied to the study of changes in behavior. Model diagram is included in Appendix D.

Reach: *How do we reach those who need the intervention?*

An educational in-service with an interactive activity was presented during training day and department meetings specifically for the intended target population--anesthesia providers.

Effectiveness: *How will we know our intervention is working?*

Labeling compliance rate determined by performing audits of labeled syringes pre- and post-intervention was the key indicator of success.

Adoption: *How do we develop organizational support to deliver our intervention?*

The anesthesia administration at this MTF is committed to enhancing unit practices for the safety of their patients. Leadership support is already in place for our intervention. We developed support from the stakeholders by demonstrating that our intervention is more compliant with TJC requirements and less work for them.

Implementation: *How do we ensure the intervention is delivered properly?*

1) The education was delivered utilizing elements based on human behavior-change theory, a format widely accepted and utilized when implementing new interventions in the workplace.
2) Staff knowledge was assessed pre- and post-education. The post-education survey administered included a Likert scale to gauge likelihood of continued behavior change.
3) We met with administration and developed a standardized plan for monitoring the project which included timelines, training, and identification of collectors.

Maintenance: *How will the intervention be incorporated so it becomes routine?*

In order to maintain the behavioral change, individualized medication labels with fill-in-the-blank time prompts were provided daily in all operating rooms by the department's anesthesia technicians. Poster cues were placed on preparation stations as a reminder of complete medication labeling practices. Re-evaluation of compliance was conducted in the same manner as the initial evaluation approximately one month post-implementation.

Project Design

General Approach

Our intervention, utilizing the RE-AIM model, followed Huis et al.'s determinants of change and addressed four different areas: knowledge, awareness, self-efficacy, and facilitation (2012). For the knowledge determinant, anesthesia staff was presented with educational training and written information on TJC requirements for medication labeling. The awareness determinant was addressed during this training by communicating the risk of non-adherence including statistics on medication errors resulting in patient harm. Self-efficacy included a guided practice where a blank medication label was provided to anesthesia providers with instructions to write all of the required information followed by feedback. The staff was then provided with the new customized pre-printed labels and asked to complete them per TJC requirements. Finally, to facilitate and maintain the behavioral change, customized pre-printed medication labels with fill-in-the-blank time prompts were provided daily to all anesthesia providers following the initial educational in-service.

Medication syringes with any label were audited over a two week period across all 10 operating rooms to determine baseline TJC medication labeling compliance. Anesthesia staff knowledge regarding TJC labeling requirements was evaluated through an anonymous questionnaire prior to the initial in-service. An educational presentation about TJC medication labeling requirements included a labeling practice exercise and was delivered during a scheduled training day and the following two weeks during the department's weekly meetings. Following the presentation, a repeat syringe collection and audit was performed approximately a month later using the same methodology. A repeat post-education anonymous staff knowledge

assessment was also disseminated and included the staff's evaluation of the new labels.

Setting and Population

The setting of this project was located at WPMC's anesthesia department. Syringe collection was performed in all 10 operating rooms that had scheduled cases and the bins were placed at the anesthesia workstations. The department consisted of 23 anesthesia providers to include anesthesiologists and certified registered nurse anesthetists. All anesthesia providers working within these operating rooms during the data collection window were instructed to dispose of used syringes in the collection bins without sharps.

Procedural Steps

Phase 1 was the baseline compliance audit (timeline included in Appendix E). Collection bins were placed in all open operating rooms and anesthesia providers were given instructions via email and visual signs to deposit all medication syringes into the bins for two weeks. At the end of each day, the bins were collected by the anesthesia technicians. Utilizing proper personal protective equipment, there was a daily audit performed by a team member who entered the data into a designated tracking spreadsheet. Syringes with any label were audited for compliance with the following TJC medication labeling requirements: medication name, strength, date prepared, time prepared, and preparer's name/initials. The tracking spreadsheet is included in Appendix F. Staff was not informed of what was being evaluated in an attempt to avoid artificially high compliance. Syringe collection modified the normal workflow slightly (dedicated collection bins for syringes only, not sharps) to maintain the safety of our team and we recognized that resistance to this change may have limited our analysis.

Phase 2 consisted of an anonymous knowledge assessment provided to all anesthesia

providers evaluating baseline knowledge of TJC labeling requirements. The answers and results were consolidated by team members. The knowledge assessment is included in Appendix G.

During phase 3, an educational presentation was delivered to anesthesia staff during a mandatory training day and repeated the following two weeks during the weekly department meeting. The presentation explained the risks of incomplete medication labels, TJC requirements for medications prepared in advance, and included a practice activity of providers labeling with both the current pre-printed stickers and a new customized sticker with blank time prompts. The presentation content is included in Appendix H. One week following the educational sessions, customized pre-printed labels were provided on a daily basis to staff who were scheduled to work in one of the 10 operating rooms; an example label page is included in Appendix I.

For phase 4, two weeks after rolling out the new medication labels, we repeated the anonymous knowledge assessment with all anesthesia providers evaluating post-education knowledge of TJC labeling requirements. This assessment also offered providers an opportunity to share perceived barriers to medication labeling and evaluation of the new labels. Results and answers were consolidated by team members. The post-education knowledge assessment is included in Appendix J.

Phase 5 was a post-intervention audit one month following education dissemination. Again, collection bins were placed in all open operating rooms and anesthesia providers were given instructions via email and visual signs to deposit all medication syringes into the bins. At the end of each day, the bins were collected from each room by the anesthesia technicians. The collection continued until the amount of syringes audited met or exceeded the total number of syringes audited during the baseline collection. Utilizing proper personal protective equipment,

there was a daily audit performed by a team member with the data inputted into a designated tracking spreadsheet. The data audited included the previously listed TJC medication labeling requirements using the same tracker.

Data Analysis Plan

The independent variable for the data analysis plan was educating the staff on medication labeling to include all components mandated by TJC and provision of pre-printed medication labels. The data source was the department's staff education records. The possible range of values was zero before the intervention was implemented and one for post-intervention. Since the values do not have any logical order, a nominal level of measurement will be utilized. The time frame for data collection included a baseline audit two weeks pre-intervention followed by an audit one month post-intervention.

The dependent variable is the medication labeling compliance percentage as dictated by TJC requirements. Compliance will require all TJC components to include medication name, strength, date prepared, time prepared, and preparer's name/initials. The dependent variable will have an outcome type of measure, therefore the variable description will be the mean percentage of medication labeling compliance. The mean will be calculated before and after the intervention is implemented. The data source was an audit of disposed syringes that fit the inclusion criteria. The possible range of values were 0 to 100%. Since the results were ranked in order, a quantitative level of measurement is indicated with an interval data type. Similar to the independent variable, the time frame for data collection included a baseline audit two weeks pre-intervention followed by an audit two weeks post-intervention. The appropriate statistical test was the paired t-test. Based on the evidence from our literature search, the decision rule was

a 75% increase in compliance to determine if our multifaceted intervention led to a change in practice.

An additional dependent variable was the percentage of correct answers during the knowledge assessment. The mean percentage of correct answers on the knowledge assessment was calculated pre- and post-educational intervention, which used an outcome type of measure. The possible ranges of values were 0 to 100% and as such, was a quantitative level of measurement with an interval data type. The time frame for collection of data was two weeks pre-intervention followed by two weeks post-intervention. The appropriate statistical test was the paired t-test. Detailed data analysis table included in Appendix K.

Potential Barriers and Dissemination Plan

Medications which are prepared and administered immediately do not require labeling. We excluded any syringes without labels as we assumed they were used for a medication that was prepared and dispensed in this manner. Staff may have disregarded instructions to use the collection bin and instead disposed of syringes in the sharps container which we were not able to evaluate. We mitigated this limit by placing our collection bin in close proximity to the normal sharps box with a label stating “Syringes only here” as a visual reminder. Staff schedules and various requirements across different departments limited our ability to capture behaviors of all staff members as some may not have been working in the main operating rooms during one or both of our collection periods. Behavioral modifications in the health care setting require a cultural change and our providers were exposed to four specific behavior change determinants: knowledge, awareness, self-efficacy, and facilitation of behavior. Knowledge and awareness dissemination was provided to all staff over several sessions, however, some staff members may

have not paid attention to the educational in-service or material that is provided to them. Additionally, guided practices required active participation from staff members, but some providers were not available due to scheduling conflicts or patient care and were unable to participate. During a mandatory training day, staff members might have avoided participation or attempted to hasten the activity, which is not conducive to behavior change. Finally, despite stocking all operating rooms with the new labels that contain prompts, old habits may have prevented an effective behavioral and cultural change.

During the entire process, multiple limitations and barriers were identified and encountered. Prior to project initiation, the pharmacy department filed multiple patient safety reports against the anesthesia department for medication mislabeling and mishandling. This led to strict reinforcement of medication labeling practices. As such, the baseline audit results may have been skewed leading to artificially higher compliance. Additionally, multiple staff suspected the baseline audits were evaluating medication labeling compliance. This could have caused practice modifications aligning with the Hawthorne Effect, which is a tendency for an individual to change their behavior due to awareness of being observed. The Hawthorne Effect was especially noted from other nurse anesthesia residents who were vaguely familiar with the project and were compliant with their medication labeling practices.

The availability of staff made it difficult to disseminate information. Our anesthesia providers had commitments other than clinical duties. These providers included members of the Air Force reserve unit who intermittently practiced at WPMC as part of their commitment and active duty members who were assigned to a teaching position nearby, but practiced at the WPMC to retain their clinical skills. Due to the variety of anesthesia staff positions, some

providers did not receive the educational in-service or complete a pre- or post-intervention knowledge assessment.

The stickers used for the customization of pre-printed labels did not have a strong adhesive to stay completely on any size of syringe. Despite trying different methods to place the stickers on the syringe (e.g. vertical versus wrapped around the diameter), we were unable to resolve the issue. Due to this, some of the post-intervention samples may have been missed as the syringes appeared unlabeled.

Following completion of the data analysis, results were presented to the department at a staff meeting and shared with the medical director via in-person meetings. Our project may be presented at the Uniformed Services University research week.

HIPAA Concerns/Ethical Considerations

There were no violations of the Health Insurance Portability and Accountability Act (HIPAA) with this intervention as patient information and records were not collected or accessed. The staff performing audits of medication labels were already trained on HIPAA policies and work within the operating room environment. Staff knowledge assessments were completed anonymously. It is possible that providers felt compelled to use the new customized medication labels because they were personalized to the individual. In order to mitigate any concern of retribution for not using the labels, no record of provider names or initials were kept during the compliance audits. Project design was reviewed by the facility's Institutional Review Board (IRB) and determined as not research and exempt from IRB approval.

Project Results

Baseline Syringe Audit

A total of 535 syringes were collected during the 2-week period. Unlabeled syringes were counted but excluded from label tracking, assuming they were used for immediate administration. Of the total 535 syringes, compliance for correct medication name was the highest at 532 (99.4%). 404 (75.5%) of syringes had strength per milliliter (mL) (concentration), 211 (39.4%) had date prepared, 182 (34%) had time prepared, 171 (32%) had preparers initials, and adherence in all labeling categories was 165 (30.8%) of the 535 total.

Post-Intervention Audit

A total of 537 syringes were collected over 2 weeks in 2022 utilizing the same methods discussed in the baseline audit. Of the 537 syringes, compliance for correct medication name was once again the highest at 536 (99.8%). 510 (95.0%) of syringes had strength per mL (concentration), 426 (79.3%) had date prepared, 290 (54%) had time prepared, 423 (78.8%) had preparers initials, and adherence in all labeling categories was 260 (48.6%) out of 535 total. This post-intervention audit showed an increase in completed medication labels of 17.8%, which was a 58% improvement from baseline compliance. Results are summarized in Figure 1.

Baseline Knowledge Assessment

A total of 19 anesthesia providers were surveyed on their knowledge of required medication labeling standards prior to education from our team. Out of 19 respondents, only two (10%) correctly stated that the TJC does not require all medication syringes to be labeled, citing the exception of immediate use medications. Nine respondents correctly listed all five criteria (45%), five listed four criteria (25%), three listed three criteria (15%), two listed two criteria (10%), and one did not respond to the question (5%).

Figure 1

Syringe Labeling Compliance

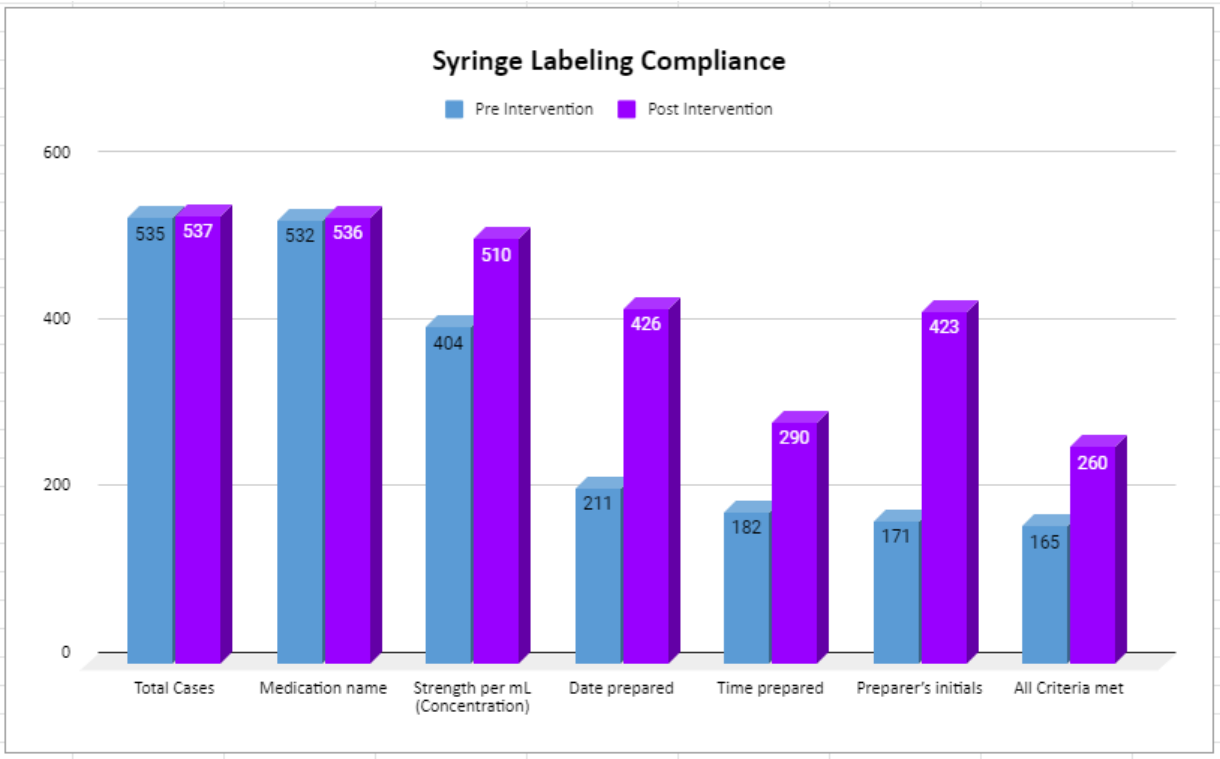
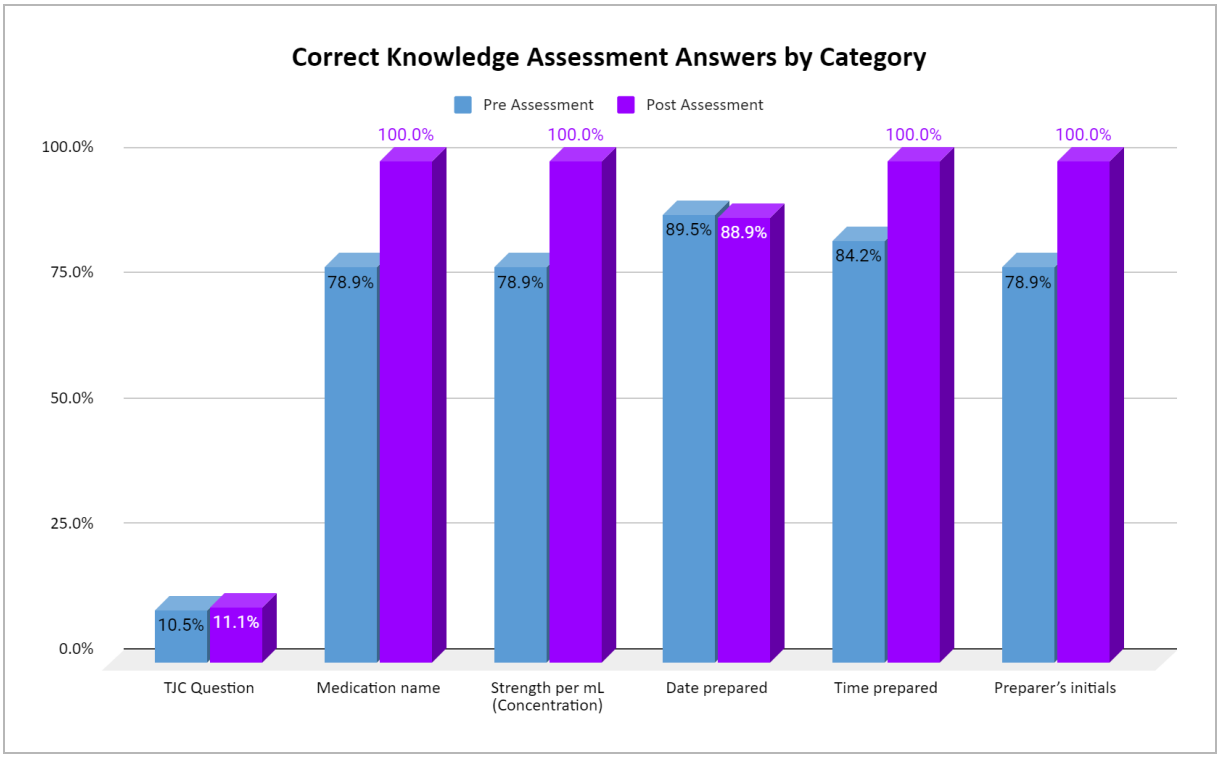


Figure 2

Knowledge Assessment



Post-Intervention Knowledge Assessment

At the time of the post-intervention knowledge assessment, many providers weren't available for participation and only nine staff members completed the assessment.
Of those respondents, 1 (11%) correctly stated that the TJC does not require all medication syringes be labeled. Eight out of nine correctly listed all five criteria for syringe labeling and one provider had four out of five correct. Results are summarized in Figure 2.

Analysis of the Results

Statistics were performed using Microsoft Excel. Target medication labeling compliance was approximately 44% following our multifaceted intervention, with 80% power and level of significance at 0.05, the minimum required sample size was calculated to be 300 syringes per audit for the study. We collected syringes over ten days for the baseline audit and collected an additional day for our post audit in order to obtain an equal or greater number of syringes. A directional one-tailed student's t-test was used to assess differences in compliance for categorical variables.

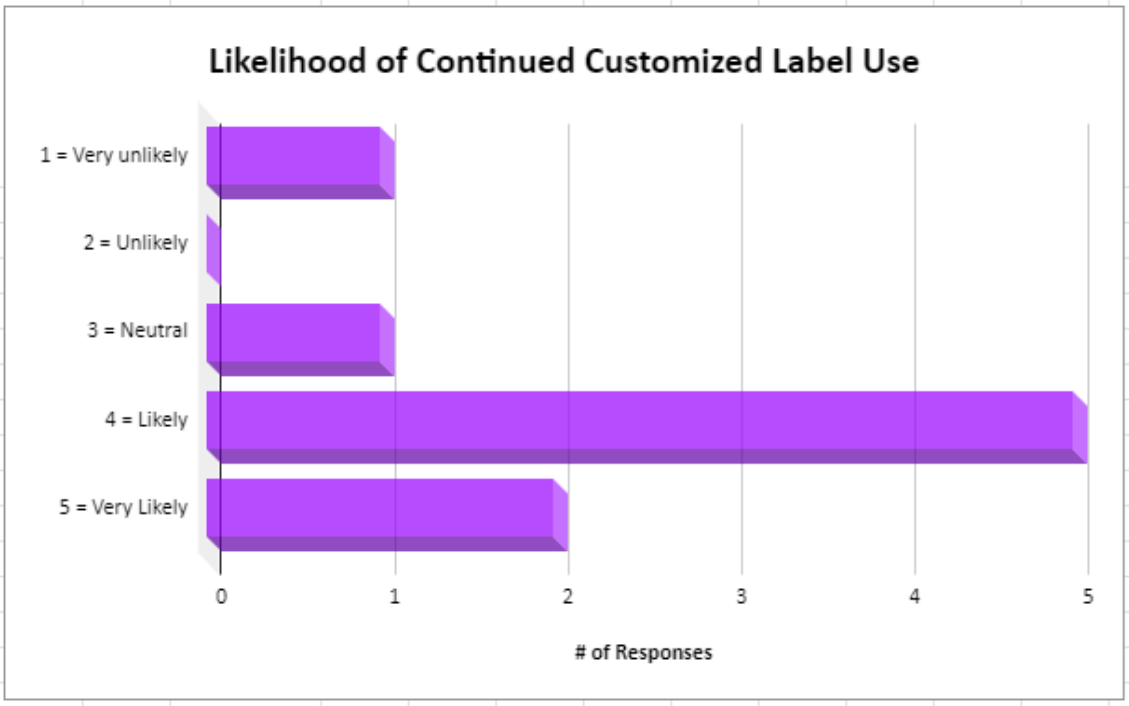
Syringe data collected had a p-value of < 0.01 for medication concentration, date, time, and preparer's initials, reflecting a high significance and suggesting the multifaceted intervention was effective. P-value for medication name was 0.157 due to the baseline high compliance rate with this component. Total compliance rate of complete medication labels increased 58 percent from 30.8 percent pre-intervention to 48.6 percent post-intervention. This increase exceeded that expected (43.9%) based on the behavior change literature we reviewed and modeled our interventions on utilizing four determinants of change (Huis et al., 2012). With the pre-knowledge result 2 out of 19 (10.5%) answering all question components correct and post knowledge result 1 out

of 9 (11.1%) answering all correct, there is a statistical improvement with education, but the small number of returned post assessments in relation to pre assessments skews the data. There was an increase in correct response rate post-intervention for four of the five label components which points to an increased staff knowledge. The question with a low correct response rate on both pre and post-intervention assessments asked if TJC required labeling of all medication syringes. It was our team's intent to use that question to ensure staff understood that medications that are prepared and immediately administered do not require a label, but our question may not have been clear and was not tested prior to presenting it to the anesthesia staff.

Overall, the label intervention was well received. Below, figure 3 shows the staff's likelihood of continued use of the customized label sheets.

Figure 3

Staff Likelihood of Continued Customized Label Use



To improve the sustainability of the project, we solicited feedback on areas for

improvement and reasons for resistance. Top complaints were time constraints, inadequate adhesiveness, and legibility (certain pens wouldn't write on provided labels). Of note, one of the respondents shared a personal belief in which, "I don't need date and time if I'm the one drawing up and administering medication." Another expressed frustration about current MTF "policy to not procure efficient and evidence-based labeling systems for the medical center (e.g., Codonics or similar system)." Potentially creating a process with a single point of failure (what if the appointed person was out sick, etc.) was a concern that was mitigated by appointing a secondary person to print labels in the morning.

Proposed Organizational Impact and Implications for Practice

Staff members increased their labeling compliance when more of the information was already completed for them. This was consistent with the literature evaluating label printing systems in that labels are complete when provided to the staff, but are not complete when any component is left to the staff to complete. Staff members are more likely to be compliant when a task reduces time spent during their workflow. Our pre-printed labels were a low-cost option that continued the change determinant of facilitation of behavior by making it easier than the previously provided sticker rolls, but still required the provider to note the time on the label. Medication label rolls were also less frequently restocked since providers received new labels each day, making it less convenient to revert to the previous process. Each provider frequently had over half of their labels remaining on the printed pages that could not be used for future days, creating excessive waste and printer ink usage. Implementing a computer-based medication labeling system would remove the providers' work entirely from labeling, might raise rates of medication labeling compliance, and reduce support staff workload.

Future Directions for Research and Practice

Our results show that changing staff behaviors involves more than just education. Department culture can be changed through a multifaceted approach addressing several determinants of change and by making the new behavior easier than the old. We believe this approach can be applied to change other behaviors using low-cost, low-tech interventions and the RE-AIM model. Our customized labels and staff education could be easily customized to a departments' needs, are low cost, and can be implemented without delay in any anesthesia department that wishes to use it. The originally desired Codonics SLS would remove the staff requirement to add information to medication labels entirely. Follow-up medication labeling compliance audits at any of the MTFs using Codonics could yield more insight to its effectiveness in increasing TJC compliance. Finally, an observational study evaluating medication errors specifically looking at wrong drug or dose pre and post medication labeling process improvement can further detail if or how medication labeling directly impacts patient care.

Conclusion

Standard medication labeling practices are cumbersome and time consuming in order to meet TJC requirements. While systems exist to streamline the medication syringe labeling process, not every hospital has a budget to obtain them. The recent transition of MTF budget oversight to the Defense Health Agency was our limitation in obtaining the Codonics SLS despite several MTFs already utilizing that system. Civilian hospitals may have many more operating rooms to supply those systems for and all hospitals' budgets have been impacted by COVID through longer hospital stays and reduced ability to offer elective procedures. In lieu of a

new labeling system, a multifaceted behavior modification program was implemented at WPMC to improve medication labeling compliance. Once pre-printed labels were provided, there was a drastic improvement in compliance with all components of a complete label. The least significant change was on the one component (time) that was left blank for the provider to complete. This phenomenon shows that process improvements work best when doing the desired behavior is easier than the existing alternative - people prefer to take the path of least resistance.

References

American Society of Anesthesiologists. (2020, December 13). *Statement on labeling of pharmaceuticals for use in anesthesiology*. Retrieved October 3, 2021, from https://www.asahq.org/standards-and-guidelines/statement-on-labeling-of-pharmaceuticals-for-use-in-anesthesiology#:~:text=Third%2C%20the%20label%20must%20include%20the%20following%20information%3A,or%20date%20%28when%20not%20used%20within%2024%20hours%29

Ang, S. B., Hing, W. C., Tung, S. Y., & Park, T. (2014). Experience with the use of the Codonics Safe Label System(™) to improve labelling compliance of anaesthesia drugs. *Anaesthesia and Intensive Care*, *42*(4), 500–506. https://doi.org/10.1177/0310057X1404200412

Australian Commission on Safety and Quality in Healthcare. (2015). *National standard for user-applied labelling of injectable medicines, fluids and lines.* https://www.safetyandquality.gov.au/sites/default/files/migrated/National-Standard-for-User-Applied-Labelling-Aug-2015.pdf#:~:text=The%20international%20Anaesthetic%20Labelling%20Standard%20%28ISO%2026825%3A2008%E2%80%93%20Anaesthetic,on%20implementing%20a%20standardised%20user-applied%20labelling%20system%20%2863%29

Bekes, J., Sackash, C., Voss, A., & Gill, C. (2021). Pediatric medication errors and reduction strategies in the perioperative period. *AANA Journal*, *89*(4), 319–324. https://www.aana.com/docs/default-source/aana-journal-web-documents-1/bekes-r.pdf?sfvrsn=91b2b257_4

Boscart, V. M., Fernie, G. R., Lee, J. H., & Jaglal, S. B. (2012). Using psychological theory to inform methods to optimize the implementation of a hand hygiene intervention. *Implementation Science, 7*(1), 77. https://doi.org/10.1186/1748-5908-7-77

Bowdle, T. A., Jelacic, S., Nair, B., Zucker, F., Bussey, L. S., Togashi, K., Yang, J. T., & Lang, J. (2019). Electronic audit and feedback with positive rewards improve anesthesia provider compliance with a barcode-based drug safety system. *Anesthesia and Analgesia, 129*(2), 418–425. https://doi.org/10.1213/ANE.0000000000003861

Codonics Patient Safety. (2021). *Our customers.* Codonics Patient Safety. Retrieved May 4, 2021, from https://www.codonics.com/customers

de Bruin, M., Viechtbauer, W., Hospers, H. J., Schaalma, H. P., Kok, G. (2009). Standard care quality determines treatment outcomes in control groups of HAART- adherence intervention studies: Implications for the interpretation and comparison of intervention effects. *Health Psychology, 28*(6), 668–674. https://doi.org/10.1037/a0015989

de Santana Lemos, C. & de Brito Poveda, V. (2019). Adverse events in anesthesia: An integrative review. *Journal of Perianesthesia Nursing, 34*(5), 978-998. https://doi.org/10.1016/j.jopan.2019.02.005

Defense Health Agency. (2019). *Quadruple Aim Performance Process: Transforming performance improvement.* https://health.mil/Reference-Center/Presentations/2019/02/11/Quadruple-Aim-Performance-Process-Transforming-Performance-Improvement

Defense Health Agency. (2021). *Defense Health Agency Strategy.*

https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency/Defense-Health-Agency-Strategy

Fraind, D. B., Slagle, J. M., Tubbesing, V. A., Hughes, S. A., & Weinger, M. B. (2002). Reengineering intravenous drug and fluid administration processes in the operating room: Step one: Task analysis of existing processes. *Anesthesiology*, *97*(1), 139–147. https://doi.org/10.1097/00000542-200207000-00020

Huis, A., Holleman, G., van Achterberg, T., Grol, R., Schoonhoven, L., & Hulscher, M. (2013). Explaining the effects of two different strategies for promoting hand hygiene in hospital nurses: A process evaluation alongside a cluster randomised controlled trial. *Implementation Science*, *8*(1). https://doi.org/10.1186/1748-5908-8-41

Huis, A., van Achterberg, T., De Bruin, M., Grol, R., Schoonhoven, L., & Hulscher, M. (2012). A systematic review of hand hygiene improvement strategies: A behavioural approach. *Implementation Science, 7*(92), 1-14. https://doi.org/10.1186/1748-5908-7-92

Jelacic, S., Bowdle, A., Nair, B. G., Kusulos, D., Bower, L., & Togashi, K. (2015). A system for anesthesia drug administration using barcode technology: The Codonics Safe Label System and Smart Anesthesia Manager. *Anesthesia and Analgesia*, *121*(2), 410–421. https://doi.org/10.1213/ANE.0000000000000256

Jensen, L. S., Merry, A. F., Webster, C. S., Weller, J., & Larsson, L. (2004). Evidence-based strategies for preventing drug administration errors during anaesthesia. *Anaesthesia*, *59*(5), 493–504.

Lexicomp. (n.d.). Succinylcholine (suxamethonium): Drug information. UpToDate. Retrieved October 15, 2021, from

https://www.uptodate.com/contents/succinylcholine-suxamethonium-drug-information?search=succinylcholine&source=panel_search_result&selectedTitle=1~149&usage_type=panel&kp_tab=drug_general&display_rank=1

Merry, A. F., Shipp, D. H., & Lowinger, J. S. (2011a). The contribution of labelling to safe medication administration in anaesthetic practice. *Best Practice & Research Clinical Anaesthesiology, 25*(2), 145–159. https://doi.org/10.1016/j.bpa.2011.02.009

Merry, A. F., Webster, C. S., Hannam, J., Mitchell, S. J., Henderson, R., Reid, P., Edwards, K.-E., Jardim, A., Pak, N., Cooper, J., Hopley, L., Frampton, C., & Short, T. G. (2011b). Multimodal system designed to reduce errors in recording and administration of drugs in anaesthesia: prospective randomised clinical evaluation. *BMJ*, *343*. https://doi.org/10.1136/bmj.d5543

Military Health System. (n.d.). *Elements of the MHS*. Retrieved April 28, 2021, from https://health.mil/About-MHS/MHS-Elements

Military Health System Review Group. (2014). *Military Health System review* (Final report to the Secretary of Defense). Department of Defense, Military Health System. https://health.mil/Reference-Center/Reports/2014/08/29/File-1-MHS-Review-Report-Executive-Summary

Nanji, K. C., Patel, A., Shaikh, S., Seger, D. L., & Bates, D. W. (2016). Evaluation of perioperative medication errors and adverse drug events. *Anesthesiology, 124*(1), 25–34. https://doi:10.1097/aln.0000000000000904

Orser, B. A., Chen, R. J., & Yee, D. A. (2001). Medication errors in anesthetic practice: A survey of 687 practitioners. *Canadian Journal of Anesthesia/Journal Canadien D'anesthésie*,

48(2), 139–146. https://doi.org/10.1007/bf03019726

Prabhakar, A., Malapero, R. J., Gabriel, R. A., Kaye, A. D., Elhassan, A. O., Nelson, E. R., Bates, D. W., & Urman, R. D. (2015). Medication errors in anesthesia. *The Journal of Medical Practice Management: MPM*, *30*(6 Spec No), 41–43.

RE-AIM. (2021). RE-AIM.org. Retrieved November 13, 2021, from https://re-aim.org/resources-and-tools/figures-and-tables/

Rothschild, J. M., Federico, F. A., Gandhi, T. K., Kaushal, R., Williams, D. H., & Bates, D. W. (2002). Analysis of medication-related malpractice claims. Archives of Internal Medicine, 162(21), 2414. https://doi.org/10.1001/archinte.162.21.2414

Simpao, A. F., & Galvez, J. A. (2015, June). Current and Emerging Technology in Anesthesia. Anesthesiology News. https://www.anesthesiologynews.com/Review-Articles/Article/06-15/Current-and-Emerging-Technology-In-Anesthesia/32822/ses=ogst

Tariq, R. A., Vashisht, R., Sinha, A., & Scherbak, Y. (2021). Medication dispensing errors and prevention. StatPearls Publishing.

The Joint Commission. (2021, March 25). *National Patient Safety Goals effective January 2021 for the Critical Access Hospital Program* [PDF]. Retrieved April 28, 2021, from https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/2021/npsg_chapter_cah_jan2021.pdf

Thomas J. J., Bashqoy, F., Brinton, J. T., Guffey, P., & Yaster, M. (2020). Integration of the Codonics Safe Label System® and the Omnicell XT® Anesthesia Workstation into pediatric anesthesia practice: Utilizing technology to increase medication labeling

compliance and decrease medication discrepancies while maintaining user acceptability. *Hospital Pharmacy.* https://doi.org/10.1177/0018578720970464

Appendix A

PRISMA Flow Diagrams

Figure A1

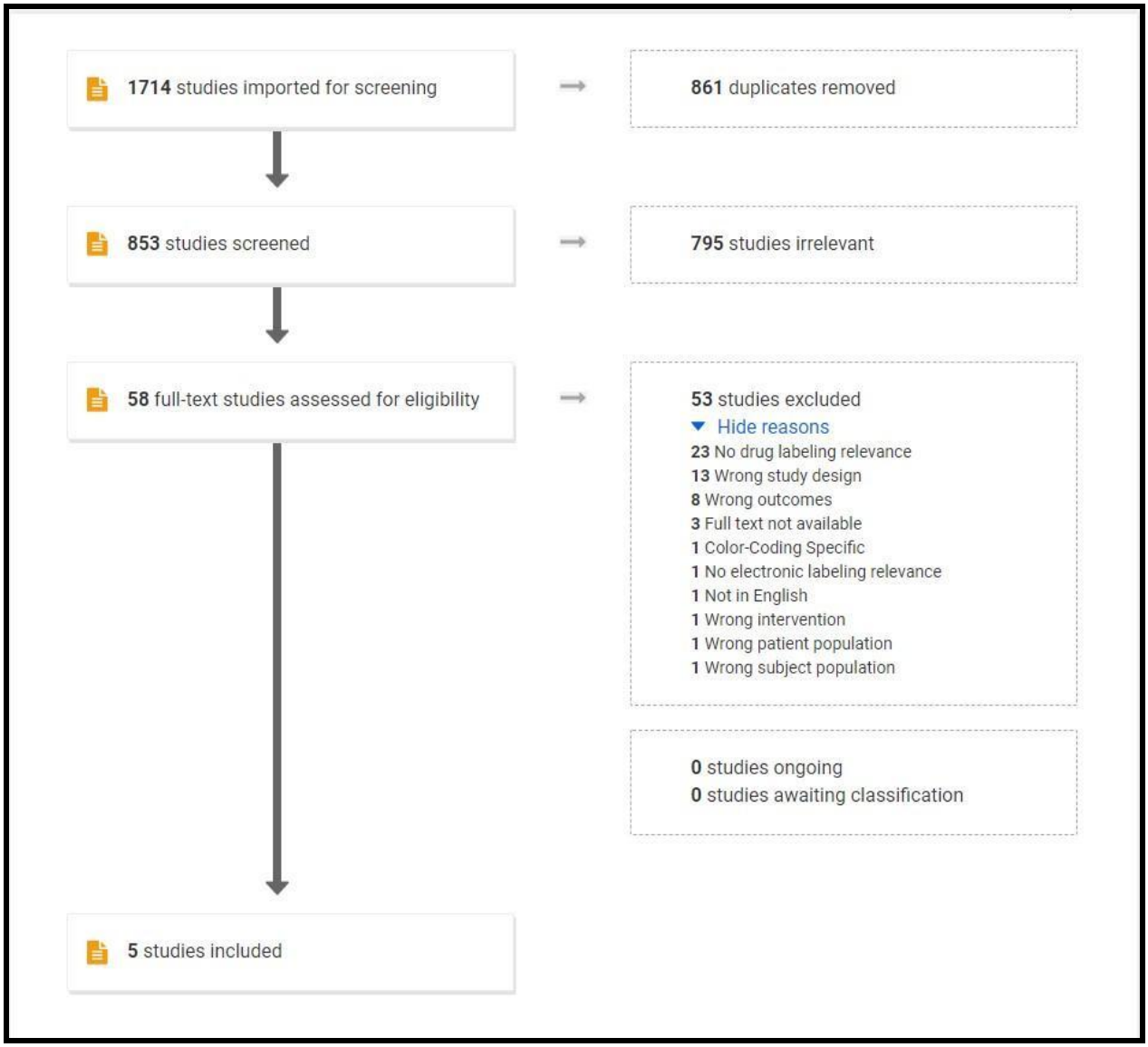
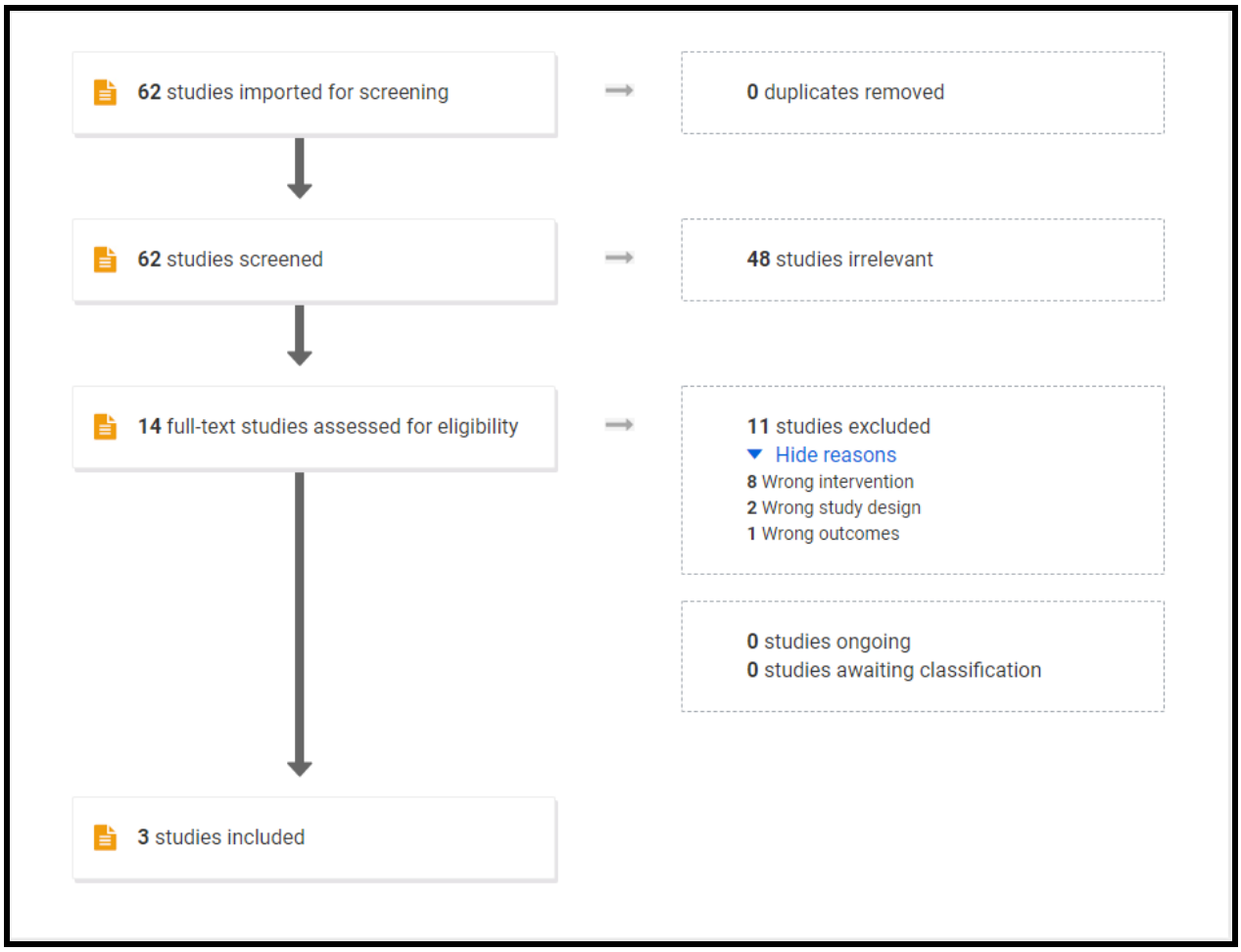


Figure A2


62 studies imported for screening
0 duplicates removed
62 studies screened
48 studies irrelevant
14 full-text studies assessed for eligibility
11 studies excluded
Hide reasons
8 Wrong intervention
2 Wrong study design
1 Wrong outcomes
0 studies ongoing
0 studies awaiting classification
3 studies included

Appendix B

Evidence Table

1st Author Name (Publication Yr)	Study Purpose/Aims	Research Questions/Hypotheses (IF different from/specifically described separately from study purpose & aims)	Study Design	Total Sample Size (How many initially, how many at final analysis?)	Sampling Plan	Independent Variables AND LEVEL OF MEASUREMENT	Dependent Variables AND LEVEL OF MEASUREMENT	Statistical Analysis - what tests were used for which research questions?	Results	Strengths (how promoted internal/external validity)	Weaknesses (biases; poorly controlled threats to internal/external validity)	LEVEL OF EVIDENCE - using JHNEBP tool (Strength and Quality)
Merry et al, 2011b	Evaluate if the SAFERSleep system (re-organized drug drawers, prefilled syringes, barcode scanning system with auditory confirmation) has an impact on errors in the recording and administration of drugs in anesthesia	There would be no significant difference between the new system and conventional methods in the rate of errors in recording or administration of medications	Data was collected from five designated operating theaters in the adult anaesthetic departments of Auckland City Hospital. Participating anaesthetists were informed and provided consent. All received formal training on the new system prior to the start of the study. Patients were informed and given the	1748 cases were managed during the trial period. 2 were excluded per patient preference, 502 excluded because no observer was available. 613 cases were on the new system, 631 used conventional methods.	Trained observers collected data in the operating theater. For the first 416 cases observers were present throughout the entire case, for the remainder they were present for most but not necessarily all of the case. Observers were present for the beginning and	Use of SAFERSleep system or conventional methods	Errors in drug administration or recording, recorded as number of incidents	Paired T test	New system had 471 errors from 5680 administrations among 566 cases (mean error rate 9.1%). Conventional system had 488 errors from 5084 administrations among 509 cases (mean error rate 11.6%). The rate of drug administration errors per 100	Observers were trained with experienced observers until consistently concordant observations were achieved. Staff were trained on the new system prior to its use.	observers present may increase vigilance and performance of staff. Study was performed in a single center.	IIB

			opportunity to decline having an observer present during their surgery. Operating theaters were randomized by week in an attempt to capture a broad case mix		end of every case				administrations was 0.16 with the new system, and 0.33 with conventional methods			
Thomas et al., 2020	Determine if medication management systems with built-in scanning and label-printing functions that integrate medication-dispensing cabinets have the potential to decrease medication administration errors by improving compliance with medication labeling	Implementation of the Codonics Safe Label System® (Codonics, Cleveland, OH), an automated labeling system (ALS), would increase compliance with best practice drug labeling guidelines while maintaining user acceptability in the operating rooms (ORs)	1. Single-center, prospective quality improvement evaluation designed to measure medication discrepancies before and after implementation of the ALS 2. Baseline audit with convenience sampling of syringes November to December 2015 with labeling elements determined by ASA, TJC, ASTM, and ISO	1. Before implementation, 696 syringes audited 2. After implementation, 433 syringes audited 3. 72 out of 85 (84%) anesthesia providers participated in anonymous user acceptability survey	1. Labeling data collected by convenience sampling of all ORs Monday through Friday before case starts until adequate number of syringes had been sampled in each phase of the study 2. Collected user acceptability data by electronic survey 3a. Children's hospital with 14 sterile ORs, 2	1. IV: Before implementation of ALS (control)→ Nominal 2. IV: Implementation of Codonics machine for labeling (intervention) → Nominal	1a. Percent of medication labeling adherence → Ratio 1b. Rate calculated as the number of missed labels divided by total number of syringes measured that day	1. Data summarized as mean plus standard deviation or percentage distribution as appropriate 2. Frequencies were calculated for categorical outcomes and presented with Wilson 95% confidence intervals 3. Likert scores for user acceptability	1. Pre-implementation: 330 of 696 syringes (47.4%; 95% CI, 43.7%-51.1%)) were either missing a label or labeling elements. 2. After implementation: 100% of all syringes received a label with the complete required labeling information (p<.0001)	1. Consistent study conditions with clearly written protocols for researchers to follow 2. Intervention transportable to real clinical environment 3. Measurements have high test-retest reliability	1. Did not cover all anesthetizing locations within the hospital 2. Study ran over a limited timeframe and results may have improved or could be a decrease in adoption over time 3. Single convenience sample of labeled syringes limited the evaluation of every syringe at all times	IIB

			3a. "Go-live" with 2 days of hands-on training to all anesthesia providers 3b. Repeated the audit of convenience sampling post implementation 5. Anonymous survey was distributed electronically to providers to assess user acceptability		cardiovascular ORs, and nine non-sterile procedure rooms 3b. Four ORs used and chosen based on their high caseloads and case types 4. Attending anesthesiologist-supervised anesthesia residents and fellows, certified registered nurse anesthetists (CRNAs), and certified anesthesia assistants (CAAs), as well as non-supervising, solo practicing attending anesthesiologists			of the intervention summarized as medians with interquartile ranges 4. Chi squared test used to compare the rate of missed labels between time periods. P values<.05 considered statistically significant	3. All respondents agreed or strongly agreed that the system was easy to use, accurate, met their needs, printed labels quickly, improved safety and efficiency, and was recommended 4. Implementation of new technology as not disruptive to workflow		4. Trainees, CRNAs, CAA, and attending anesthesiologists may not be generalized to different hospital settings 5. Verbiage of survey questions was positive, however, there were opportunities to give low scores for any of the questions asked 6. Convenience sampling may cause bias	
Ang et al., 2014	1. Test the Codonics Safe Labeling System to identify risks,	None specified	1. Baseline survey 2a. Observational	1. Baseline survey with 25 anesthesia cases during	1. One operating room was selected for	1. IV: Conventional labeling	1. Percent of compliance with medication	1. Chi square testing used to assess	1. Baseline study: Compliance in all	1. One consistent trained observer	1. Possible Hawthorne effect with presence of	IB

	benefits, and usability 2. Determine if there was a difference in compliance or medication error rate between conventional labeling versus the use of the Codonics machine		study consisted of randomized study with conventional labeling versus the use of the Codonics machine with data collected over two months in 2012 2b. Labeling technique was randomized daily with blinded draw of paper slips drawn by a third party who was not involved in the study 3. User acceptability survey designed with input from the university Human Factors Department with 39 anesthesiologists and residents who had hands-on experience with Codonics machine during	which 212 syringes were prepared from 223 drugs 2a. Observational study with 47 cases with 330 syringes prepared; 75 syringes were immediate use (doesn't require labeling per TJC standards) therefore 255 syringes used for determining labeling compliance 2b. Sample size calculated to be 81 syringes per arms for the randomized study 3. Twelve primary anesthesiologists and sixteen assisting anesthesiologists (e.g. trainees)	consistency of cases and ease of logistics 2. The operating theater selected conducted cases only for obstetrics and gynecology to facilitate the homogeneity of data collection 3. Anesthesiologists were assigned to this room by blinded rostering staff 4. For allowance for data collection, a minimum of 100 samples for each arm of the study in one major OR EXCLUDED: If drugs drawn were administered immediately as labeling not required	(control)→ Nominal 2. IV: User of Codonics machine for labeling (intervention) → Nominal	label → Ratio 2. Eight subcategories included for labeling compliance → Nominal	difference in compliance for categorical variables with differences considered statistically significant if $p<0.05$ 2. 80% power and level of significance at 0.05	categories of labeling was 58.4%; Compliance for correct name was 100%; Individual category compliance ranged from 74.7% to 100%; No near-misses or medication errors detected by observer or reported by provider 2. Randomized study: Conventional group compliance was 63.8% with twelve syringes not labeled at all Codonics group compliance at 98.6% ($p<0.0001$) No near-misses	who stayed throughout case to observe for medication errors and labeling practices in the baseline study and observational study 2. None of providers were assigned to Codonics more than once during study, which minimized any learning effects 3. Randomization 4. Consistent study conditions	observer in the room 2. Baseline audit performed with a wide variety of cases and randomized study with more restriction to type of cases and one operating room 3. Observation done on elective cases only	

			the baseline audit and randomized trial		under these circumstances; Medications administered by infusion or used directly from manufacturer's drug preparation				or medication errors reported in this part of study by either observer or provider 3. 55% states demonstration was most effective training method Perceived ease of learning: easy to learn and to remember how to use machine Majority agree machine was easy to scan, prepare and print, and more legible with better adherence versus conventional Most participants dissatisfied			

									with increased workload and increased time of drug labeling 43.6% were satisfied with machine			
Jelacic et al., 2015	1. To assess the baseline medication labelling compliance (color and content) rate in the Operating Room versus the labelling compliance (color and content) rate after implementing the Codonics Safe Label System (SLS) 2. To compare anesthesia providers' utilization of a syringe barcode scanning tool, which provided auditory and visual confirmation of drug and linked	None specified	1. Observational audits were performed before SLS implementation over 5 weeks, then post implementation audits of 2 cardiothoracic ORs where SLS were placed over 7 weeks. 2. Prospective measurement of syringe barcode scanning system use for 13 weeks, then implemented incentive and measured use again for another 8 weeks	1. Pre-SLS: 327 syringes (127 prepared by anesthesia/200 by pharmacy) Post-SLS: 312 syringes (101 prepared by anesthesia/211 by pharmacy) 2. 12 attending anesthesia providers monitored for use of syringe barcode scanning tool	1. Pre-SLS: Audited syringes in ORs without anesthesia knowledge Post-SLS: Audited syringes in 2 CT ORs with SLS machines without anesthesia knowledge 2. In 2 CT ORs with SLS machine, all medications administered by anesthesia compared against syringe barcode scanning tool	1. IV: SLS machine (with or without) → Nominal 2. IV: Incentive (Pre or post) → Nominal	1. Percent of syringe labels compliant with content and color requirements → Ratio 2. Percent of syringe barcodes scanned prior to medication administration → Ratio	1. Confidence interval 2. Hypothesis testing pre-post comparison	1. Prior to SLS implementation, syringes labeled by anesthesia providers were only 36% compliant with required criteria; post implementation that rate rose to 93%. All of the Codonics labels were compliant but due to technical problems some labels were handwritten and those	1a. Audits were completed without anesthesia providers' knowledge b. Differentiated those made by the clinician vs those created by the pharmacy supporting the ORs	1. Only 3 SLS machines were available so while all ORs were audited initially, only 2 were included post implementation 2. Only 12 anesthesia providers included	IIIB

	into the hospital's charting system, prior to drug administration before and after implementing an incentive								had a 42% compliance rate. 2. Syringe scanning pre-incentive was 25% but rose to 58% after incentive was offered			
Bowdle, et al., 2019	Determine whether electronic audit and feedback with positive rewards to improve adherence with a barcode-based drug safety system were effective (defined as >=50% rate of scanning) and sustained (defined as an effect maintained for >=6 months)	Can electronic audit and feedback with positive rewards improve anesthesia provider adherence with a barcode-based drug safety system?	1. Prospective observational study without a control group 2. Interrupted time series analysis, sometimes known as quasi-experimental time series analysis 3. During November 2014 to February 2016 ("pre-intervention phase"), baseline data collected during which scanning of the syringe barcodes was not promoted 4. Implemented a program to	From November 2014 to March 2017, accumulated 60,197 cases performed by 88 attending anesthesiologists, 65 CRNAs, and 148 residents. Total number of syringe drug administration was 653,355	1. Performed at their academic medical center, which has approximately 35 anesthetizing locations, and performs approximately 23,000 anesthetic procedures per years 2. Used an anesthesia care team approach in which the attending anesthesiologists are paired with residents, fellows, or	1. IV: Electronic auditing and feedback → Nominal 2. IV: Incentives/Positive rewards (coffee cards) → Nominal	1. Percent of provider compliance in utilizing the barcode-based drug safety system → Ratio	1. Fitted a segmental regression model to determine if there was a significant difference in intercept ("jump") between the monthly aggregate scan rate at the end of pre-intervention phase and start of post-intervention phase to reflect any short-term change 2. Conducted a sensitivity	1. Average scanning performance improved from 8.7% of syringe barcodes scanned during the baseline period from November 2014 to February 2016 to 64.4% scanned during the period September 2016 to March 2017 ($p<.001$) 2. Pre-intervention phase was	1. Thoughtful inclusion and exclusion criteria to prevent confounders 2. Consistent study conditions to prevent confounders 3. Feasibility and user-friendliness system	1. Hawthorne effect might have contributed to improvement of post-intervention phase scan rate 2. Study results may have been confounded by changes in practices over the course of study, other than the intervention (unable to identify any specific confounders and possible that there	IIB

			improve adherence to include lecture and video materials, feedback of individual performance data to providers in the form of monthly email reports, and rewards for top performance in the form of coffee gift cards only for the first 2 months 5. During March and April 2016 ("rollout phase"), providers were messaged with learning materials to encourage syringe barcode scanning 6. "Post-intervention phase" from September 2016 to March 2017		certified registered nurse anesthetists (CRNAs) 3. EXCLUDED: Barcode scans with altered time stamps as adherent barcode scanning because the drug is supposed to be scanned immediately before administration; when the time is altered, it is assumed that the drug was given first and the syringe was scanned later; Did not include phenylephrine boluses because providers sometimes administer boluses from the infusion			analysis to evaluate if the "jump" stayed significant when replacing post-intervention phase scan rate by the "projected" scan rate at the start of the post-intervention phase 3. Confidence Interval	associated with a scan rate of 13.4% (95% CI, 12.2%-14.4%) in first month (pre-intervention intercept) and on average decreased by 0.27% (95% CI , 0.14%-0.41%; p<.001) per month throughout the period (pre-intervention slope) 3. Post-intervention phase was associated with a scan rate of 64.4% (95% CI, 62.2%-66.5%) in first month and on average decreased by 0.87% (95%		were confounders that were not recognized) 3. Variability with residents due to monthly rotating assignments to other 4 hospitals whereas the barcode-based drug safety system is unique to this university medical center and not implemented in their other hospitals 4. Barcode scanning system occasionally malfunctioned or barcodes did not scan properly 5. Using an anesthesia team approach (pair of providers	

			7. Rate of adherence determined by comparing the number of syringe drug administrations with and without barcode scanning, which is recorded by the Smart Anesthesia Manger support software		pump rather than a syringe, and they are unable to distinguish the two modes				CI, 0.034%-1.72 %; p=0.42) per month (post-interve ntion slope) 4. There was a significant increase of 55.4% (95% CI, 52.7%-58.0 %; p<.001)		with an attending anesthesiolog ist and a resident or CRNA) therefore cannot distinguish which provider actually scanned a syringe or failed to scan a syringe - individual performance data always reflect the performance of a team	
Huis et al., 2012	Determine which interventions are most effective in increasing hand hygiene and classify them on the basis of their determinants of behavior change	Same as purpose	Reviewed all articles from prior systematic review, plus database searches of CINAHL, MEDLINE, EMBASE, Cochrane, and others. Search was limited to studies of human beings and had to include	41 articles were included in this analysis	Stated in study design	Number of determinants of change addressed	Percent change in hand hygiene compliance	Relative difference calculated as (the results from the intervention group after the intervention minus the results from the control group after the intervention)	The median effect was a relative improvemen t of 17.6 in performance . The effect size from one controlled study addressing two determinants was 25.7.	Evaluated interventions based on a different model than previously used. Evaluated a total of 41 studies.	Evaluating interventions that were already done vs creating an intervention and testing it. It is not possible to compare differences between hospitals/unit s where	IB

			healthcare workers in hospital settings, interventions strategies aimed at improving hand hygiene, a comparison, and an outcome of hand hygiene behavior					divided by the results from the control group after the intervention	The relative difference increased from 42.3 in the three studies addressing three determinants to 43.9 for the two studies addressing four determinants. The relative difference was 49.5 for the three studies that addressed five determinants. No controlled study addressed six determinants. The only controlled study addressing		interventions were tested.	

									seven determinants showed less impact on short-term effectiveness			
Huis et al., 2013	Which components of two hand hygiene improvement strategies were associated with increased nurses' hand hygiene compliance, a state of the art strategy (SAS) or both state of the art strategy and team/leaders directed strategy (TDS)	Which strategy increased compliance? SOS or SOS + Team/leaders?	A process evaluation of a cluster randomised controlled trial which used four sets of measures: effects on nurses' hand hygiene compliance, adherence to the improvement strategies, contextual factors, and nurses' experiences with strategy components.	67 total, break out of 20 for second intervention, so 47 and	Stated in study design	SAS Strategy TDS Strategy Nominal	Percent change in hand hygiene compliance Ordinal	Analysis of variance (ANOVA) and multiple regression analysis Likert for surveys	Changes in nurses' hand hygiene compliance were positively correlated with experienced feedback about their hand hygiene performance ($p < 0.05$). In the long run, several items of the components 'social influence' (i.e., addressing each other on undesirable hand hygiene behaviour $p < 0.01$), and 'leadership' (i.e., ward	Audits w/o participants knowledge Follow up	1) 48% survey response rate 2) 10 wards opted out of the TDS	IIA

									manager holds team members accountable for hand hygiene performance $p < 0.01$) correlated positively with changes in nurses' hand hygiene compliance.			
Boscart et al., 2012	Identify nurses' and administrators' perceived barriers and facilitators to current hand hygiene (HH) practices	Explore barriers and facilitators of a HH behavior change	A qualitative design using semi structured key informant interviews used to collect data. Key informant interviews consist of qualitative in-depth interviews from a range of people who have firsthand knowledge about the phenomena in the practice setting. They can provide insight on the nature of	Director of care, unit manager, an infection control specialist, and nurses were key informants There is no firm and fast rule regarding the appropriate sample size in interpretive descriptive research. The vast majority of studies using this approach are	Inclusion criteria included part-time or full-time employees on the designated unit and providing direct care. The infection control specialist, director of care for the facility and unit manager responsible for the intervention unit were invited.	N/A	N/A	The Theoretical Domains Framework (TDF) was used to explore the purpose of the study	The behavior-change domains included were knowledge, skills, social professional role and identity (self-standards), beliefs about capabilities (self-efficacy), beliefs about consequences (anticipated outcomes/attitudes), motivation	Each interview followed the same protocol to ensure quality control The interviews were conducted in a private setting using a semistructured guide, audiotapes, and transcribed verbatim. Each	Potential social desirability bias, the use of a simple coding scheme, and small sample from on hospital unit	IIIA

			problems and give recommendations for solutions	likely to be relatively small. Using principles for deciding saturation in theory-based interview studies, a minimum sample size for initial analysis was determined to be six nurses and three administrators The predetermined designation of the intervention unit limited the sample size since the facility employs only one director of care, three infection control specialists, and the intervention unit employs 24 nurses					and goals (intention), memory, attention, and decision process, environmental context and resources (environmental constraints), social influences (norms), emotion, behavioral regulation, nature of the behaviors One of the biggest discrepancies between the two groups was related to the beliefs about consequences and domain. Another major difference was in the social	transcript was reviewed by the interviewer to ensure accuracy and inclusion of expressive detail		

									influences domain The apparent differences between administrators and nurses need to focus on the provision of support and mentoring nurses, rather than solely improving the frequency of HH			

Appendix C

BCA Worksheet

BUSINESS CASE with VALUE BASED CARE ASSESSMENT
Proposed Title for Project/Initiative/Opportunity to Improve
Improving Medication Labeling Compliance in Military Treatment Facility Operating Rooms Amongst Anesthesia Providers
Opportunity Statement
Medication errors due to mislabeled medication syringes prepared by anesthesia providers is a pressing issue in the operating room. Military Treatment Facilities (MTF) must meet The Joint Commission (TJC) standards and reduce the risk of wrong drug or wrong dose medication errors by adhering to labeling standards. Evaluating if anesthesia providers' labeling practices are in compliance with TJC will determine a need to implement evidence-based practices such as the Codonics Safe Label System (SLS).
Business Opportunity/Objectives
The goal is to optimize medication syringe labeling methods to comply with TJC requirements. This will improve patient safety by decreasing medication errors that may lead to patient injury, harm, or death. Mitigating medication errors will also maintain deployment readiness as well as reduce financial burden that results from wasted medication and unintended treatment from adverse events (Nanji et al., 2016). ● Macro objectives: The big picture of this business case is to evaluate medication syringe labeling compliance by anesthesia providers working within the operating room. Continual noncompliance will support the necessity of investing in an evidence-based labeling machine such as the Codonics SLS – a point-of-care equipment that has been shown to efficiently print medication labels compliant with TJC recommendations. ● Micro objectives: o Implementation of audits to track performance pre- and post- staff education on TJC medication labeling requirements. o Distribution of a TJC medication labeling requirement PowerPoint. o Rate staff likelihood to change their labeling practices post-education.
Potential Impact of the Initiative/Project
Investigation is needed to determine if anesthesia provider medication labeling practices necessitate a change. The metric used will assess staff education effectiveness by calculating the percentage of medication labeling

in compliance with TJC standards pre-education and post-education. Labeling requirements include the name of the medication, strength, amount of medication or solution, diluent and volume, expiration date and time, time prepared, and preparer's initials. Our benchmark for success is a 75% compliance rate, the rate other anesthesia groups achieved utilizing the Codonics SLS (Simpao & Galvez, 2015).

As part of the Quadruple Aim, improved readiness is at the center of better health, better care, and lower cost. A total military force is dependent on quality care, eliminating waste, and reducing generators of ill health. MTFs are accredited by nationally-recognized organizations such as TJC, which have stringent criteria for safe and effective patient care. These criteria will improve patient safety while eliminating waste and excess costs (Defense Health Agency, 2019). Improving medication labeling compliance also aligns with the MHS Review Group's (2014) focus on reducing medication errors which is a leading cause of safety investigations. MTFs that do not provide optimal patient care may stray from the Quadruple Aim by causing patient harm and increased cost from wasted medication or patient treatment following medication errors – all factors that impede the readiness of a healthy military force.

Alternatives (Courses of Action) Chosen for Analysis

1. Equip all ten operating rooms with the point-of-care Codonics SLS
2. Investing in pre-filled syringes for medications utilized the most in emergent situations
3. *"Status Quo"*: Maintain the current practice of handwritten syringe label stickers where the provider is responsible for writing some or all of the required components

Analysis of Alternatives

Alternative 1:	Stocking all ten operating rooms with the point-of-care Codonics SLS

Pros	**Cons**
• **Benefits:** Provides quick and convenient labeling by generating a color-coded sticker to include all TJC medication labeling requirements (Ang et al., 2014). • **Added safety feature:** As the drug vial is scanned, there will be audible verification of the drug name and concentration giving anesthesia providers an extra barrier of safety (Jelacic et al., 2015). • **Cost saving/avoidance:** It will attenuate the risk of wrong drug/dose errors that result from improper labeling. This will mitigate the cost of wasted medication, unintended treatments or extended hospital stay, and malpractice claims (de Santana Lemos & de Brito Poveda, 2019). • **DOD adopted:** Currently there are 22 MTFs that have fully integrated the Codonics SLS into their workflows under a distribution and pricing agreement (DAPA) with the	• **Cost:** The cost to restock supplies for ten machines is $172 for each label/ink bundle - a total of $1720. ○ Additional replacement parts may need to be ordered for repair or maintenance (Codonics quote, personal communication, September 28th, 2021). • **Startup resources:** The startup cost of stocking ten operating rooms may quickly deplete fiscal spending. The total cost

<table>
<tr><td>Defense Logistics Agency (DLA). In addition, 48 Veterans Affairs entities have adopted the Codonics system (Codonics, 2021).
● Adaptability: The machine settings provide users the ability to change the printer settings so each label contains the exact specifications required for TJC compliance (Jelacic et al., 2015).
● Availability: Each operating room is equipped with a medication labeling system.
● Training: The system is intuitive and doesn't require extensive training for use (Ang et al., 2014).
● Patient satisfaction: Improving patient safety and reduction of adverse reactions will provide patients with a sense of security, which can be fruitful for the facility's reputation and attract more beneficiaries to obtain health care within the Military Health System.
● Accreditation: Improved compliance with TJC standards will impact the future accreditation of the facility (TJC, 2021).
● Repair Costs: A representative is available to assist staff in troubleshooting without any additional costs (Codonics, 2021).</td><td>including machine, software and accessories is $104,400 (Codonics quote, personal communication, September 28th, 2021).
● Culture change: Staff may be hesitant, frustrated, or resistant to new procedural changes that alter their work flow (Thomas et al., 2020).
● Unreliability: As with any equipment, technological malfunction may cause provider frustration, adding more time to medication preparation.
○ A loss of power supply will require a couple of minutes for the machine to reset resulting in a loss of efficiency (Ang et al., 2014).</td></tr>
<tr><td>Alternative 2:</td><td colspan="2">Invest in pre-filled syringes for medications utilized the most in urgent/emergency situations</td></tr>
<tr><td colspan="2">Pros</td><td>Cons</td></tr>
<tr><td colspan="2">● Cost saving/avoidance: Pre-filled syringes are shelf stable 6 times longer than provider prepared syringes. For instance, a succinylcholine in a pre-filled syringe is stable for 90 days whereas provider-prepared is only safe to use for 24 hours. The cost of each vial of Succinylcholine drawn up for ten operating rooms per day is estimated to be $24 (Lexicomp, n.d.).
● Convenience: Anesthesia providers will save time from drawing up medications from a vial and handwriting labels for each syringe. Pre-filled syringes are convenient to use and provide consistent concentrations.</td><td>● Cost: Pre-filled syringes:
<table><tr><th>Drug</th><th>Price per syringe ($)</th></tr><tr><td>Ephedrine 5 mg/mL in 5 mL Syringe</td><td>23.70</td></tr><tr><td>Ephedrine 5 mg/mL in 10 mL Syringe</td><td>41.50</td></tr><tr><td>Succinylcholine 20 mg/mL in 5 mL Syringe</td><td>19.00</td></tr><tr><td>Succinylcholine 20</td><td>30.00</td></tr></table></td></tr>
</table>

<table>
<tr>
<td>

- **Patient satisfaction:** Improving patient safety and reduction of adverse reactions will provide patients with a sense of security, which can be fruitful for the facility's reputation and attract more beneficiaries to obtain health care within the MHS.
- **Accreditation:** All pre-filled syringes are created using TJC compliant labels which impacts the future accreditation of the facility (TJC, 2021).
- **Ease of Adaptability:** Pre-filled syringes will not interrupt work flow or require additional staff training.

</td>
<td>

mg/mL in 10 mL Syringe	
Phenylephrine 100 mcg/mL in 10 mL Syringe	6.65
Ketamine 10 mg/mL in 5 mL Syringe	6.65

(Central Admixture Pharmacy Services quote, personal communication, October 21, 2021)

- **Limited Medications:** Pre-filled syringes are only available for certain medications.
- **Availability:** Compounding pharmacies are experiencing supply chain issues that may interrupt drug supply. Backup vials will need to be kept on hand.

</td>
</tr>
<tr>
<td>Alternative 3:</td>
<td colspan="2">"Status Quo": Maintain the current practice of handwritten syringe label stickers where the provider is responsible for writing some or all of the required components</td>
</tr>
<tr>
<td colspan="2">Pros</td>
<td>Cons</td>
</tr>
</table>

• **Cost saving/avoidance**: Maintaining the status quo may prevent large financial spending on equipment and may be the most cost effective fiscal alternative • **Culture change:** Already the standard of care, therefore there will not be a need to train staff to implement new policies and procedures. This will allow anesthesia providers the ability to continue their familiar practices (Thomas et al., 2020).	• **Standard of practice:** The current standard is not improving labeling compliance. This may place patients at risk for sentinel events. • **Cost saving/avoidance:** Inefficient spending due to wasted medication, treatment or extended hospital stays following adverse events, as well as malpractice claims (de Santana Lemos & de Brito Poveda, 2019)**.** Annually, the US spends more than $40 billion due to medication errors (Tariq et al., 2021). • **Patient satisfaction:** Incidences of poor patient outcomes will lead beneficiaries to seek out other facilities if they fear for their health and lose trust in the MHS. These patient outcomes also have the possibility of attracting negative media attention, which can poorly reflect on the MHS. • **Patient safety:** The number one priority in all health care systems is patient safety!
Assumptions	

1. Info points needed to compare alternatives:
- We would need to implement metrics to track performance and compliance
- Cost of equipment includes maintenance and restocking

2. Time frame for info collection
- We need to establish a baseline measure before providing education
- Evaluation of pre-intervention and post-intervention compliance will be performed over the same amount of time
- Post-intervention measurement will occur after a pre-designated time has elapsed

3. Providers would prefer to save time

4. Providers are amenable to processes that improve patient safety

5. It takes more than 7 seconds for a provider to prepare one label

Recommendation and Rationale

Recommendation

Alternative #1: Stock all ten operating rooms with the point-of-care Codonics SLS

Rationale

After comparing the pro/con analysis for each of the alternatives, alternative #1 will be the best option to increase the probability of medication labeling compliance amongst anesthesia providers. Stocking all ten operating rooms will provide consistency and convenience in medication labeling. The added audible safety feature, in addition to the automatic labeling from the machine, indicates this alternative will be the best intervention to implement.

Value Based Care - Investment Required by the Organization and the Associated "AlVALUE" or $ GAINED.

Volume projection based on: As of March 2020, the average # of OR cases per year was 4500. An estimated 6 labels are used per case.

4500 OR cases per year x 6 syringes per case	27,000
Total	**27,000 labels**

II. *Reimbursement calculated for:*

In 2002, the average cost of a preventable inpatient medication malpractice claim was $377,000 (Rothschild et al., 2002). The average perioperative medication error rate was about 5% (Nanji et al., 2016). Given 4500 OR cases per year, there could be up to 225 claims opened. The "reimbursement" or savings reflects the amount if a conservative 5 claims were paid out.	$ 1,885,000

III. *Costs:*

Variable Costs:

Proprietary labels and ink average of 0.15 per label (0.15*6)*(4500)	$ 4,050
Software update costs	$ 0 inc. with purchase
Total	**$ 4,050**

Fixed Costs:

Machines x 10, media and accessories	$104,400
Labor: There are currently 23 providers. At an estimated average wage of $75/hr per provider, the two-hour training cost is provided.	$3,450
Overhead (use of electricity, computers, HVAC, etc.)	$2,000 est
Off-network formulary laptop	$2,000 est
Total	**$111,850**

IV. *Forecasted P&L statement:*

Revenues:

Potential cost savings from averted litigation	$1,885,000
Time Savings: 7 seconds per label (Jelacic et al. 2015) x 6 labels per case = 53 hours provider time given back to patient care. Amount figured at $75/per hour.	$3,975
Total revenues	**$1,888,975**

Costs:

Variable costs	$4,050
Fixed costs	$111,850
Total costs	**$ 115,900**

PROJECTED PROFIT **$ 1,773,075**

Risks and Mitigation Plan	
Risks	**Plan**
1. Staff change behaviors and have an artificially high compliance during audits	1. Staff will not be informed of rationale for syringe collection
2. Staff workflow is temporarily slowed when first using Codonics SLS	2. Staff will be trained prior to system activation with "super users" available to assist as needed for the first two weeks after implementation
3. Staff are resistant to using the new system	3. Education will be provided with notification that current label rolls will be removed from work stations one month after Codonics SLS activation.
4. Equipment failure will require a backup method of labeling	4. The current medication label rolls will continue to be maintained in the anesthesia supply room for this event

Implementation Plan		
Phase 1:	Baseline Audit	
Milestone Description:	Syringes will be collected from all operating rooms for a defined period (2 weeks) and all syringes with any label on them will be evaluated for compliance with TJC requirements.	
Deliverables	Due Date	Accountable Person
Initial data table of syringe labeling compliance	28 Feb 2022	Hodgen/Albright

Resources Needed		
Collection bins in each of the ten operating rooms. Man hours required to record compliance of each syringe with each TJC requirement on a spreadsheet		
Expected Level of Benefit		
This phase will show current practice and culture of the anesthesia department in regards to medication labeling compliance.		
Phase 2:	Baseline knowledge assessment	
Milestone Description:	Baseline knowledge assessment will be distributed to and collected from staff anonymously	
Deliverables	Due Dates	Accountable Person
Baseline knowledge level	1 Mar 2022	Gruss/Nunnery/Huynh
Resources Needed		
Word application, printer, dedicated collection location, manpower to summarize results		
Expected Level of Benefit		
This will evaluate how effective education is to convince providers to label medication syringes completely, as well as identify existing barriers that the team may not have considered.		
Phase 3:	Educational Presentation	
Milestone Description:	Create and disseminate an educational presentation to the anesthesia department and conduct medication labeling activity	
Deliverables	Due Dates	Accountable Person
Educational presentation	31 Mar 2022	Gruss/Nunnery/Huynh
Resources Needed		
PowerPoint, current and updated medication labels		
Expected Level of Benefit		
All staff will be provided with one educational product and have an opportunity for guided practice to increase self-efficacy and familiarize themselves with the new pre-printed medication stickers.		

Phase 4:	Post-education knowledge assessment	
Milestone Description:	An anonymous, voluntary questionnaire will be distributed to staff to assess post-education knowledge, how likely they are to change their labeling practices, and if they are unlikely to change what is preventing a change in practice.	
Deliverables	Due Dates	Accountable Person
Post-education knowledge level and summary of perceived barriers	30 Apr 2022	• Gruss/Nunnery/Huynh
Resources Needed		
Word application, printer, dedicated collection location, manpower to summarize results		
Expected Level of Benefit		
This will evaluate how effective education is to convince providers to label medication syringes completely, as well as identify existing barriers that the team may not have considered.		
Phase 5:	Post-education Audit	
Milestone Description:	Syringes will be collected from all operating rooms for a defined period (2 weeks) and all syringes with any label on them will be evaluated for compliance with TJC requirements.	
Deliverables	Due Dates	Accountable Person
Post-education data table of syringe labeling compliance	30 May 2022	Hodgen/Albright
Resources Needed		
Collection bins in each of the ten operating rooms. Man hours required to record compliance of each syringe with TJC requirements on a spreadsheet		
Expected Level of Benefit		
This phase will show whether practice and culture of the anesthesia department has changed in regards to medication labeling compliance following education on TJC requirements		

NOTE: Modified from Harvard Business Review Press. (2011). *Pocket mentor: Developing a business case.* Boston: Author (pp 82-85

Appendix D

RE-AIM Model Diagram

RE-AIM (2021)

Appendix E

Timeline

Project Year 1 (2021)												
Activity/Month	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**
USUHS VPR Submission and Approval												X
Site IRB Submission and Approval												X
Project Planning -Task 1: Background data collection -Task 2: Project design -Task 3: BCA				X	X	X	X	X	X	X	X	

Project Year 2 (2022)												
Activity/Month	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**
USUHS VPR Submission and Approval	X											
Site IRB Submission and Approval	X											
Project Implementation/Data Collection -Task 1: Baseline audit -Task 2: Baseline knowledge assessment -Task 3: Education dissemination -Task 4: Post-education knowledge assessment -Task 5: Post-education audit		X	X	X	X							
Data Analysis -Task 1: Evaluate data with statistician						X	X	X				

-Task 2: Evaluate audits against one another -Task 3: Summarize data analysis												
Dissemination -Task 1: Poster development -Task 2: Presentation development -Task 3: Present outcomes to stakeholders									X	X	X	X

Appendix F

Syringe Audit Spreadsheet

Syringe #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Medication name															
Strength per mL (Concentration)															
Date prepared															
Time prepared															
Preparer's initials															
# Criteria Met	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
# of unlabeled syringes															
NS syringe:															
Criteria Met = 1															
Criteria Missing = 0															

Appendix G

Knowledge Assessment

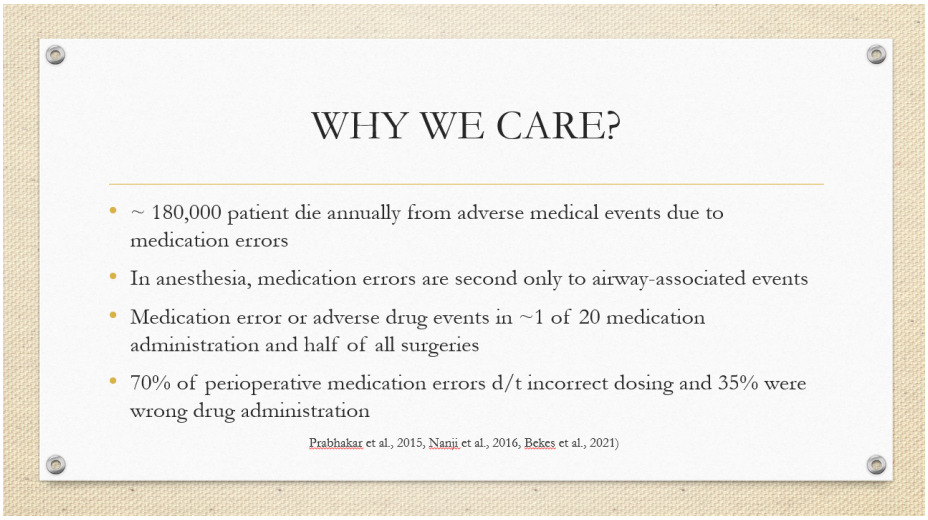
Does The Joint Commission require all medication syringes to be labeled?

Yes No

What components does TJC require on medication labels?

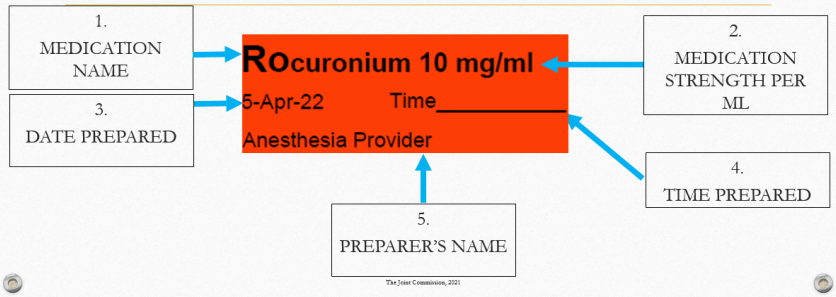
Appendix H

Staff Educational Presentation



Exercise, Exercise, Exercise!

WHAT ARE THE REQUIREMENTS?



REFERENCES

1. Prabhakar, A., Malapero, R. J., Gabriel, R. A., Kaye, A. D., Elhassan, A. O., Nelson, E. R., Bates, D. W., & Urman, R. D. (2015). Medication errors in anesthesia. The Journal of Medical Practice Management: MPM, 30(6 Spec No), 41–43.
2. Nanji, K. C., Patel, A., Shaikh, S., Seger, D. L., & Bates, D. W. (2016). Evaluation of perioperative medication errors and adverse drug events. Anesthesiology, 124(1), 25–34. https://doi:10.1097/aln.0000000000000904
3. Bekes, J., Sackash, C., Voss, A., & Gill, C. (2021). Pediatric medication errors and reduction strategies in the perioperative period. AANA Journal, 89(4), 319–324. https://www.aana.com/docs/default-source/aana-journal-web-documents-1/bekes-r.pdf?sfvrsn=91b2b257_4
4. The Joint Commission. (2021, March 25). National Patient Safety Goals effective January 2021 for the Critical Access Hospital Program [PDF]. Retrieved April 28, 2021, from https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/2021/npsg_chapter_cah_jan2021.pdf

Appendix I

Customized Label Sheet

Anesthesia Provider Name 5-Apr-22

Glycopyrrolate 0.2 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Glycopyrrolate 0.2 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Glycopyrrolate 0.2 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Glycopyrrolate 0.2 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Succinylcholine 20 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Succinylcholine 20 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Succinylcholine 20 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Succinylcholine 20 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Rocuronium 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Rocuronium 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Rocuronium 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Rocuronium 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Neosynephrine 100 mcg/m 5-Apr-22 Time_____ Anesthesia Provider Name	Neosynephrine 100 mcgml 5-Apr-22 Time_____ Anesthesia Provider Name	Neosynephrine 100 mcg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Neosynephrine 100 mcg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Ephedrine 5 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Ephedrine 5 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Ephedrine 5 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Ephedrine 5 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Esmolol 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Esmolol 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Labetalol 5 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Labetalol 5 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Propofol 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Propofol 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Propofol 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Propofol 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Ketamine 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Ketamine 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Ketamine 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Ketamine 10 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Precedex 2 mcg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Precedex 2 mcg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Precedex 2 mcg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Precedex 2 mcg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
FentaNYL 50 mcg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	FentaNYL 50 mcg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	FentaNYL 50 mcg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	FentaNYL 50 mcg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Dilaudid 0.2mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Dilaudid 0.2mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Dilaudid 0.2mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Dilaudid 0.2mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Versed 1 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Versed 1 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Versed 1 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Versed 1 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Zofran 2 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Zofran 2 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Zofran 2 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Zofran 2 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Decadron 4 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Decadron 4 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Decadron 4 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name	Decadron 4 mg/ml 5-Apr-22 Time_____ Anesthesia Provider Name
Lidocaine 2% 5-Apr-22 Time_____ Anesthesia Provider Name	Lidocaine 2% 5-Apr-22 Time_____ Anesthesia Provider Name	Lidocaine 2% 5-Apr-22 Time_____ Anesthesia Provider Name	Lidocaine 2% 5-Apr-22 Time_____ Anesthesia Provider Name

Appendix J

Post-Education Knowledge Assessment

Does The Joint Commission require all medication syringes to be labeled?

Yes No

What components does TJC require on medication labels?

How likely are you to change your medication labeling practices to incorporate the customized label sheets?

(1-5 scale, 1 = not likely at all; 3 = neutral; 5 = very likely)

1 2 3 4 5

What barriers prevent you from complete medication labeling?

Appendix K

Data Analysis Table

Unit of Analysis	Variable Name		Variable Description and type of measure	Data Source	Possible Range of Values	Level of Measurement	Time Frame for Collection	Statistical Test	Decision Rule
Event	**IV** (in book referred to as descriptive variable)	Medication Labeling Education	<u>Description:</u> Anesthesia providers received an educational intervention on medication labeling in compliance with TJC standards A pre and post-education knowledge assessment will be disseminated and collected <u>Measure Type:</u> Process	Staff education department records	0 = before intervention implementation 1= after intervention implementation	Nominal	Before PowerPoint staff education: 2 weeks After PowerPoint staff education: 2 weeks	None	N/A
	DV (in book referred to as outcome variable)	% medication labeling compliance by anesthesia providers per all	<u>Variable Description:</u> Mean % compliance of medication labeling to meet	Audit of medications disposed in a designated bin	0 to 100%	Interval	Before PowerPoint staff education: 2 weeks	Paired t-test or Wilcoxon signed-rank test (if issues	Based on literature, increased compliance rate to 75%

		of TJC standards (medication name, strength, amount of medication or solution, diluent name and volume, expiration date and time, time prepared, and preparer's initials for all medications prepared in advance"	TJC standards-calculate the mean for all staff BEFORE and AFTER the educational intervention Measure Type: Outcome				After PowerPoint staff education: 2 weeks	with normal distribution)	
	DV (in book referred to as outcome variable)	% correct on knowledge assessment	Variable Description: Mean % correct on knowledge assessments-calculate the mean for all staff BEFORE and AFTER the educational intervention Measure Type: Outcome	Knowledge assessment	0 to 100%	Interval	Before staff education: 2 weeks After staff education: 2 weeks	Paired t-test or Wilcoxon signed-rank test (if issues with normal distribution)	N/A

Among anesthesia providers at Wright-Patterson Medical Center, how does the implementation of a multifaceted intervention compared to standard practice affect compliance with medication labeling standards?

Appendix L

Team Mentor (Committee Membership) Agreement Form

Appendix C: Daniel K. Inouye Graduate School of Nursing
DNP Project Team Mentor (Committee Membership) Agreement Form

DOCTOR OF NURSING PRACTICE PROJECT
DNP Project Clinical Question and Team Mentor (Committee Membership) Agreement Form

Graduation Year: 2023

Name(s) of DNP Project Student Team:

1. Maj Kelli Gruss Phase II Site: AGCNS ☐ FNP ☐ PMHNP ■ RNA ☐ WHNP ☐
2. Maj H. Tammy Huynh Phase II Site: AGCNS ☐ FNP ☐ PMHNP ■ RNA ☐ WHNP ☐
3. Capt Shannon Nunnery Phase II Site: AGCNS ☐ FNP ☐ PMHNP ■ RNA ☐ WHNP ☐
4. _____ Phase II Site: AGCNS ☐ FNP ☐ PMHNP ☐ RNA ☐ WHNP ☐
5. _____ Phase II Site: AGCNS ☐ FNP ☐ PMHNP ☐ RNA ☐ WHNP ☐
6. _____ Phase II Site: AGCNS ☐ FNP ☐ PMHNP ☐ RNA ☐ WHNP ☐

The tentative title of the DNP Project Proposal for this student group is:
Improving Medication Labeling Compliance in the Wright-Patterson Medical Center Operating Room Amongst Anesthesia Providers.

Committee Approved DNP Project Clinical Question:
Among anesthesia providers at Wright-Patterson Medical Center, how does the implementation of a multifaceted intervention compared to standard practice affect compliance with medication labeling standards?

Names of DNP Project Team Mentors *(type the name and obtain signatures)*:

I agree to serve as a member of the DNP Project Team (Team Mentors) for the above DNP Student Project Team. As a Project Team Mentor, I agree to the duties and responsibilities outlined within the DNP Project Manual which include but are not limited to the provision of consultation and guidance supporting the entire DNP project journey and to ensure the DNP project is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation.

Form Version: 1 Jun 2016

Appendix C: Daniel K. Inouye Graduate School of Nursing
DNP Project Team Mentor (Committee Membership) Agreement Form

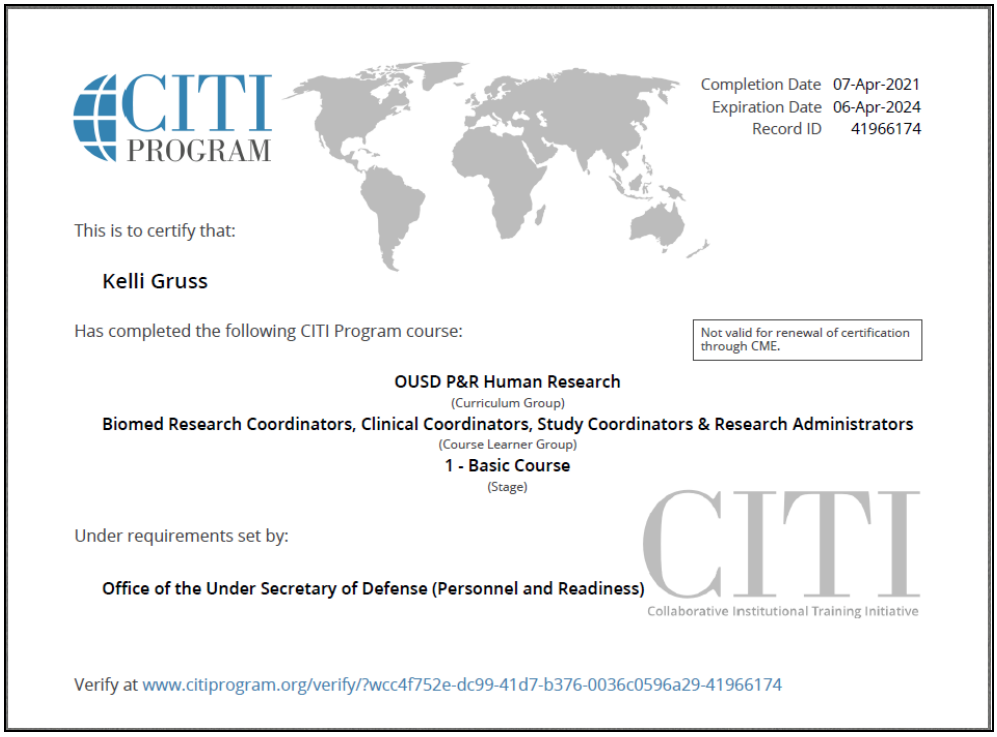
NOTE: You may have 3-4 DNP Team Mentors [committee members including your DNP Senior Mentor (Chair)]. The Phase II Site Director may also be a member of the group, as well as other USUHS faculty or others who may serve as content experts. All non-USUHS faculty selected as a Team Mentor must be approved by the DNP Project Director.

Senior Mentor (Chair):	Maj Mark Albright	Signature:	ALBRIGHT.MARK.CHRISTOPHE.1043964646	Date:	1/23/2023
Team Mentor (Committee):	Lt Col R. Kyle Hodgen	Signature:	HODGEN.RONALD.KYLE.1111803354	Date:	1/23/2023
Team Mentor (Committee):		Signature:		Date:	
Team Mentor (Committee):		Signature:		Date:	

Form Version: 1 Jun 2016

Appendix M

CITI Certificates



CITI PROGRAM

Completion Date 07-Apr-2021
Expiration Date 06-Apr-2024
Record ID 41966174

This is to certify that:

Kelli Gruss

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

OUSD P&R Human Research
(Curriculum Group)
Biomed Research Coordinators, Clinical Coordinators, Study Coordinators & Research Administrators
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wcc4f752e-dc99-41d7-b376-0036c0596a29-41966174

CITI PROGRAM

Completion Date 07-Apr-2021
Expiration Date 06-Apr-2024
Record ID 41984101

This is to certify that:

Hai McMannon

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

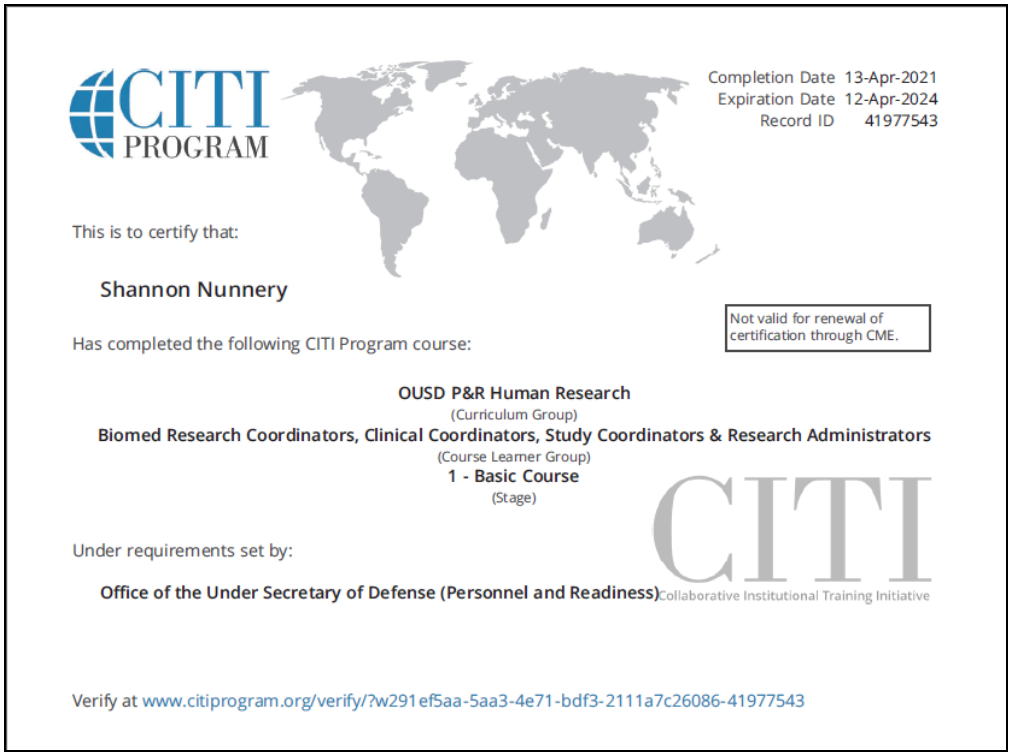
OUSD P&R Human Research
(Curriculum Group)
Biomed Research Coordinators, Clinical Coordinators, Study Coordinators & Research Administrators
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w638339ad-fdae-4c9c-9ae0-b5d772f238e7-41984101



CITI PROGRAM

Completion Date 13-Apr-2021
Expiration Date 12-Apr-2024
Record ID 41977543

This is to certify that:

Shannon Nunnery

Not valid for renewal of certification through CME.

Has completed the following CITI Program course:

OUSD P&R Human Research
(Curriculum Group)
Biomed Research Coordinators, Clinical Coordinators, Study Coordinators & Research Administrators
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w291ef5aa-5aa3-4e71-bdf3-2111a7c26086-41977543

Appendix N

USU (VPR) Form 3202N

USUHS FORM 3202N
DANIEL K. INOUYE GRADUATE SCHOOL OF NURSING
EVIDENCE-BASED PRACTICE/PERFORMANCE IMPROVEMENT PROPOSAL

VPR Date Stamp

Project Number: GSN-61-13072 (VPR will assign)

Project Title: Improving Medication Labeling Compliance in Military Treatment Facility Operating Rooms Amongst Anesthesia Providers

SECTION A: STUDENT POC INFORMATION

1. Name (Last, First, MI): Gruss, Kelli, D — Student E-mail: kelli.gruss@usuhs.edu
2. Home Address: [redacted] — Cell Number: [redacted]

SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION

3. Name (Last, First, MI): Albright, Mark, C
4. Telephone: [redacted] Fax: [redacted] E-mail: mark.albright@usuhs.edu
5. USUHS Building/ Room No.: Wright-Patterson Medical Center

SECTION C: PROJECT INFORMATION

6. Attach the Abstract for the proposal, including the following sections: Site Location of the Project, Title, Authors, Background or Problem/Issue, Clinical Question/Purpose, Project Design, Anticipated Organizational Impact/Implications for Practice and also include the Proposed Timeline. Single space the abstract and use Times New Roman font, size 12.
7. Is this proposal related to an active research project of the Chair/Senior Mentor identified in Section B? ☐ Yes ☒ No
   If yes, complete below; if no, proceed to Part 8.
   Project Number:
   Project Title:
   Project Start Date: Project End Date:
8. Anticipated period of performance: Project Start Date: 2/14/2022 Project End Date: 3/31/2022
9. Performance Site(s): Wright-Patterson Medical Center
10. Does this project involve any classified information? (Contact the USUHS Security Office for guidance) ☐ Yes ☒ No
11. Do you have a funding source for this project? ☐ Yes ☒ No ☐ NA
    If yes, specify the funding agency and the amount provided:

SECTION D: SIGNATURES

The following signatures attest to the validity of the above information:

GRUSS.KELLI.D.1364299555 Digitally signed by GRUSS.KELLI.D.1364299555 Date: 2022.01.22 07:25:39 -05'00'
Student (Project Point of Contact for the Group) (Signature and Date)

ALBRIGHT.MARK.CHRISTOPHE.1043964646 Digitally signed by ALBRIGHT.MARK.CHRISTOPHE.1043964646 Date: 2022.01.25 16:30:45 -05'00'
Chair/Senior Mentor (Signature and Date)

[redacted]
Chair/Program Director (Signature and Date)

BARBER.KENNETH.DOUGLAS.1177263644 Digitally signed by BARBER.KENNETH.DOUGLAS.1177263644 Date: 2022.10.24 10:53:07 -04'00'
Chair/Program Director (Signature and Date)

[redacted]
DNP Project Director or PhD Director (Signature and Date)

SEIBERT.DIANE.C.1084932279 Digitally signed by SEIBERT.DIANE.C.1084932279 Date: 2022.10.28 20:51:34 -04'00'
Associate Dean for Academic Affairs, GSN (Signature and Date)

SIMMONS.ANGELA.MARIE.1143313375 Digitally signed by SIMMONS.ANGELA.MARIE.1143313375 Date: 2022.10.28 11:54:45 -04'00'
Associate Dean for Research, GSN (Signature and Date)

ROMANO.CAROL.A.1032050294 Digitally signed by ROMANO.CAROL.A.1032050294 Date: 2022.10.28 11:49:04 -04'00'
Dean, DKI Graduate School of Nursing (Signature and Date)

In light of the above signatures, the project is approved.

WOODBERRY.MITCHELL.WAYNE.1060957114 Digitally signed by WOODBERRY.MITCHELL.WAYNE.1060957114 Date: 2023.01.06 13:41:02 -05'00'
USUHS Vice President for Research

Date

USUHS Form 3202N (VPR) - Revised Sep 2015 v1.2
Previous versions are obsolete

Appendix O

MTF IRB/PI Letter of Determination

DEFENSE HEALTH AGENCY
88TH MEDICAL GROUP - WRIGHT-PATTERSON
4881 SUGAR MAPLE DRIVE
WRIGHT-PATTERSON AIR FORCE BASE, OH 45433

20 December 2021

MEMORANDUM FOR 88 SGC/SGCJ
ATTN: MAJ KELLI GRUSS

FROM: WPMC HUMAN RESEARCH PROTECTION PROGRAM

SUBJECT: Human Research Protection Program (HRPP) Research Determination

1. Your project proposal has been reviewed by an exempt determination official of the Wright-Patterson Medical Center (WPMC) HRPP.

Protocol #: FWP20210030N
Title: Improving Medication Labeling Compliance in a Military Treatment Facility Operating Room Amongst Anesthesia Providers
PI: Maj Kelli Gruss

Type of Review: Research Determination
Assurance #: DoD Assurance DHA000016 / DHHS FWA 00000609

Determination: Not Research
Date of Determination: 20 December 2021

2. The WPMC HRPP has determined that this project does not meet the criteria to be considered research in accordance with 32 CFR 219.102. Therefore, research protocol approval and oversight by an IRB is not required. Any substantive changes to the activity may affect the study status and must be reviewed by the WPMC HRPP.

3. This determination does not grant permission to conduct the project; this authority lies with 88th Medical Group leadership.

4. If you have any questions regarding this determination please call me at [redacted] or e-mail frederick.h.funke.civ@mail.mil.

FUNKE.FREDERICK.H.1077709025 Digitally signed by FUNKE.FREDERICK.H.1077709025 Date: 2021.12.20 12:02:08 -05'00'

FREDERICK H. FUNKE, Civ, DAF, CIP
WPMC Human Protections Administrator

Appendix P

PAO Clearance /Level of Dissemination Classification

USU
Uniformed Services University

Gruss, Kelli <kelli.gruss@usuhs.edu>

88 MDG Case Completed: Case Number 88MDG-2023-0007
1 message

SAF.PA.Security.and.Policy.Review@us.af.mil <SAF.PA.Security.and.Policy.Review@us.af.mil> Thu, Mar 9, 2023 at 8:34 AM
Reply-To: pamela.a.piccoli.civ@health.mil
To: kelli.gruss@usuhs.edu, frederick.h.funke.civ@health.mil, pamela.a.piccoli.civ@health.mil

88 MDG has completed the review process for your case on 09 Mar 2023:

Subject: Improving Medication Labeling Compliance in Wright-Patterson Medical Center Operating Room Amongst Anesthesia Providers (Manuscript)

Originator Reference Number: 88MDG-2023-009
Case Reviewer: Pamela Piccoli
Case Number: 88MDG-2023-0007

The material was assigned a clearance of CLEARED on 09 Mar 2023. If you have any questions concerning your case, please contact Pamela Piccoli pamela.a.piccoli.civ@health.mil.

Appendix Q

DNP Project Completion Verification Form

Appendix G: Daniel K. Inouye Graduate School of Nursing
DNP Project Completion Verification Form

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled:

Improving Medication Labeling Compliance in the Wright-Patterson Medical Center Operating Room Amongst Anesthesia Providers

was completed at: Wright-Patterson Medical Center

by the following student(s):

(type student name)	*(signature)*	*(date)*
Maj Kelli Gruss	GRUSS.KELLI.D.1364299555 Digitally signed by GRUSS.KELLI.D.1364299555 Date: 2023.04.06 10:08:26 -04'00'	04/06/2023
Maj H. Tammy Huynh	HUYNH.HAI PHUONG.T.1385168132 Digitally signed by HUYNH.HAI PHUONG.T.1385168132 Date: 2023.04.06 10:08:17 -04'00'	04/06/2023
Capt Shannon Nunnery	NUNNERY.SHANNON.1162321192 Digitally signed by NUNNERY.SHANNON.1162321192 Date: 2023.04.06 11:49:07 -04'00'	04/06/2023

The DNP Practice Project Team verifies that the following components of the DNP project, accomplished by the above students, is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation:

- Presentation of DNP project to the leadership/stakeholders at the Phase II Site,
- Abstract/Impact Statement (*Appendix F*), and
- DNP Project written report.

Verified by:

	(type name)	*(signature)*	*(date)*
Senior Mentor:	Maj Mark Albright	ALBRIGHT.MARK.CHRISTOPHE.1043964646 Digitally signed by ALBRIGHT.MARK.CHRISTOPHE.1043964646 Date: 2023.04.07 10:20:49 -04'00'	04/07/2023
Team Mentor:	Lt Col R. Kyle Hodgen	HODGEN.RONALD.KYLE.1111803354 Digitally signed by HODGEN.RONALD.KYLE.1111803354 Date: 2023.04.07 12:52:34 -04'00'	04/07/2023
Team Mentor:			
Phase II Site Director:			

For RNA Students only *- add the following additional signature for final verification of project completion:*

CDR Kenneth Barber	BARBER.KENNETH.DOUGLAS.1177263644 Digitally signed by BARBER.KENNETH.DOUGLAS.1177263644	10APR2023
RNA Project Director *(type name)*	*(Signature)*	*(Date)*

Form Version: 26 Aug 2017/30 Mar2020