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Using a Cost Benefit Analysis to Support the Development of a Comprehensive Business Model for a Pre-Filled, Pre-Labeled, Pre-Diluted, Sterilely Packaged, Ready-to-Use, Syringe-Based Anesthesia Delivery System

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USING A COST BENEFIT ANALYSIS TO SUPPORT THE DEVELOPMENT OF A COMPREHENSIVE BUSINESS MODEL FOR A PRE-FILLED, PRE-LABELED, PRE-DILUTED, STERILELY PACKAGED, READY-TO-USE, SYRINGE-BASED ANESTHESIA DELIVERY SYSTEM

by

Lance Brandon Kennedy

Abstract of a Capstone Project
Submitted to the Graduate School
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ABSTRACT

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The foundation of Certified Registered Nurse Anesthetists' (CRNAs) entire profession is built on the ability to provide anesthetic services using a variety of medications in the safest, most efficient, cost-effective way possible. The purpose of this capstone is to address, via a comprehensive cost benefit analysis, whether pre-filled syringe drug trays are a more cost-effective way to address problems as compared to vial-filled drug trays and to implement the necessary transitions in order to improve outcomes. There are a number of identifiable problems related to anesthesia medication delivery via vial-filled medication, including increased cost of healthcare, decreased patient safety to provider inconvenience, increased medication errors, and increased contamination. The method of medication delivery has gained the attention of significant governing bodies such as the Joint Commission of Healthcare Organizations (JCAHO), Centers for Disease Control (CDC), and American Association of Nurse Anesthetists (AANA), just to name a few. The best methods for change were evaluated in order to facilitate the most optimal quality improvement. According to the AANA, "the available information is sufficient to promote the implementation of pre-filled or premixed syringes in anesthesia departments

to reduce the number of adverse drug events (ADEs) and become compliant with the Joint Commission, and Institute of Medicine" (Brown, 2014, pp. 465-469).

The future change in anesthesia drug delivery is undeniable, and the data provide clearly defined recommendations and guidelines supporting the use of pre-filed syringes. Providing medications in pre-filled syringes would reduce medication errors and treatment delays, improve patient safety, and effectively meet the expectations, recommendations, and guidelines of governing entities (Fahimi et al., 2008). "When you look at the impact of the initiative on quality and safety for the patients, it's [just] what's right to do" (Blum, 2013, p. 3).

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A Capstone Project
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at The University of Southern Mississippi
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LIST OF ABBREVIATIONS

AANA	American Association of Nurse Anesthetists
ADE	Adverse Drug Event
AHRQ	Agency for Healthcare Research Quality
CDC	United States Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CRNA	Certified Registered Nurse Anesthetist
EBA	European Board of Anesthesiology
EBSCO	Elton Bryson Stephens Company
HQA	Hospital Quality Alliance
ICU	Intensive Care Unit
IOM	Institute of Medicine
IV	Intravenous
JCAHO	Joint Commission of Healthcare Organizations
MDA	Medical Doctor Anesthesiologist
NQF	National Quality Forum
PICO	Population, Intervention, Comparison, Outcome
PDSA	Plan-Do-Study-Act
WHO	World Health Organization

CHAPTER I

INTRODUCTION

Statement of the Problem

Imagine, for a moment, a happy and mischievous four-year-old little boy, full of life and laughter. His name is Jacobi Hill. Imagine his big brown eyes lighting up as he lets out an infectious laugh. Imagine his contagious smile as he hid his mom's car keys, as he often did (Burns, 2010). Imagine a cool crisp morning as his parents take him for 'routine' dental surgery. Fast-forward to the OR and now imagine this dream turns into a nightmare. Imagine his anesthesia provider struggling to ventilate the little boy after he has been rendered incapable of protecting his own airway. The anesthesiologist's left hand is firmly securing the mask to the little boys face, and his right hand is applying positive pressure to the bag attempting to break what is seemingly a laryngospasm, but he is still unable to ventilate. Anyone in anesthesia knows that this little boy needs a life-saving, short acting paralytic, like succinylcholine. The problem is that at this point, it would require it to be "drawn up" from the vial and with both hands occupied, someone else, less familiar with the drugs and too inexperienced to prepare the drug quickly and safely, must attempt to do so when every second that passes is another second without oxygen. The little boy is finally given the appropriate medication, intubated, and taken to intensive care unit where he remains for the next few days until he eventually dies. This is so tragic, but the worst part is that it was potentially preventable. Had there been a system in place that would allow immediate administration of life-saving drugs without the risk of medication waste and medication errors, perhaps little Jacobi Hill still be alive.

Background and Significance

The intent of this comprehensive cost benefit analysis is to provide the highest quality medical supplies to healthcare providers in order to improve the quality of healthcare. Identifiable problems related to anesthesia medication delivery via vial-filled medication include: (1) Significant increased healthcare cost related to medication waste and dilutional drug errors (U.S. National library of Medicine National Institute of Health, 2011); (2) Increased possibility of contamination and infection due to drawing up medication without the use of a sterility hood, while frequently under hurried conditions. Also, some medications have a very short time to expiration when drawn up by the provider, as opposed to under sterile pharmacy conditions (Fahimi et al., 2008); and (3) During an acute condition such as a laryngospasm, hypotension, or bradycardia, time to draw up emergency drugs takes away precious time from the patient, and can result in frightful negative outcomes (Adapa et al., 2012).

Additionally, governing entities such as the Joint Commission, CDC, and the AANA have recommendations and guidelines that support pre-filled syringes, and make it virtually impossible to practice without using them. The 2010 National Patient Safety Goals state that "when a drug is drawn into a syringe or otherwise used from its original container it must be immediately administered. 'Immediate administration' means with no intervening steps or functions prior to administration" (The 2010 National Patient Safety Goals, 2010, p. 5). The CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care states that "Injections [should be] prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids or contaminated equipment" (CDC, 2013, p. 6). This means that

medication should be drawn and labeled outside of patient areas, including the operating room. Furthermore, according to the AANA (2014), the use of pre-filled or premixed medication and electronic documentation have been shown to reduce the number of Adverse Drug Events (ADEs) by as much as 21%, and, according to the IOM, approximately $2 billion is spent annually on ADEs in hospital settings. This would mean a $420,000,000 decrease in healthcare cost just on ADEs alone. Moreover, the Joint Commission standard MM.05.01.07 states that medication preparation should either be done by a pharmacist or under the direct supervision of a pharmacist. The AANA concludes that the savings justifies the cost, and "the available information is sufficient to promote the implementation of pre-filled or premixed syringes in anesthesia departments to reduce the number of adverse drug events and become compliant with the Joint Commission, and Institute of Medicine" (Brown, 2014, pp. 465-469).

Each of these problems has a significant cost attached to them. If anesthesia providers would be willing to make an effort to move toward compliance with the governing bodies' guidelines and recommendations, they would simultaneously promote safety, improve outcomes, and decrease the cost of healthcare. The purpose of the capstone is to address, via a comprehensive cost benefit analysis, whether pre-filled syringe drug trays are a more cost-effective way to address these problems as compared to vial-filled drug trays and, if so, to find methods to implement necessary transitions.

Concept Analysis

Anesthesia medication delivery affects the lives of every patient who ever needs to undergo surgery and require anesthetic services. In constructing a concept analysis, the first step is selecting a concept, then determining the aim of the analysis, followed by

identifying uses for the concept, determining the defining attributes, identifying model cases, antecedents, and consequences, and finally, defining empirical referents (Butts & Rich, 2015). Two models are used to evaluate the differences between vial-filled anesthesia drug trays and pre-filled syringe anesthesia drug trays. The first quality improvement model utilized is the Plan-Do-Study-Act (PDSA) cycle (The Deming Institute, 2013). PDSA is a four-tier problem-solving model used for quality improvement. When applying the PDSA model it is important to consider what our goal is and to consider if the change is an improvement. The goal is to develop a comprehensive business model for a pre-filled, pre-labeled, pre-diluted, sterilely packaged, ready-to-use syringe based anesthesia delivery system. A cost benefit analysis will identify and validate the results of the syringe based anesthesia delivery system, and determine that it is indeed a substantial improvement.

The PDSA model has two cycles. Cycle one involved the planning phase, including brainstorming and implementing the proposed changes to improve the anesthesia drug delivery to improve outcomes via pre-filled, pre-diluted, sterilely packaged, ready-to-use syringes in an anesthesia delivery system. Next, commonly used drugs, their dilutions, and their organization and cost, were identified and compared against pre-filled syringes.

The results were then analyzed, costs were compared, and evidence identified an obvious cost benefit in multiple areas including medication waste, medication errors, decreased time of anesthetic induction, and increased patient safety. Further study is needed to identify more specifically how much dilutional errors cost on a national, regional, and local facility level, but, approximately $2 billion is spent annually on ADEs

in hospital settings, and the AANA cites the use of pre-filled syringes to decrease this by as much as 21% (Brown, 2014, pp. 465-469). Therefore, healthcare costs stand to be decreased, at the very least $420,000,000 annually. The final portion of this model involved initiating a business plan and the considering of standardization options. Once cycle one is complete and results are analyzed, the PDSA cycle 2 can begin and an evaluation can be made to consider which areas were successful and which areas were not.

The second model used to evaluate the difference between vial-filled medication trays and pre-filled medication trays pertains to transitions within professional practice. The transition process begins when life events create the need for change. The management of these transitions has profound effects on life, well-being, and health. The transitions model can be used to optimize the nursing profession and better prepare nurses to work efficiently in a diverse healthcare system (Young and Wilkerson, 2010).

There are three phases in the concept of the Transitions Model according to Young and Wilkerson (2000). Phase one is the 'ending phase', which is the release of familiar ways. The ending phase requires the person in transition to recognize the need for change, and be willing to let go of the status quo to step outside of their comfort zone and be open to other possibilities. The second phase is the 'neutral phase' and it involves ambiguity and disequilibrium. Here, accustomed ideas are disrupted and lost, and the transitions require the use of personal, interpersonal, and various environmental means to assist the change process. The third phase is the 'reorientation phase'. In this phase, feelings of synchronization and harmony are restored, creating new meaning and independence. There is an acceptance of the new challenges and a sense of ownership in

the new situation. Positive outcomes include restitution, encouragement, security, and preservation. Change is difficult and often resisted, however, change is necessary in order to grow and improve outcomes (Young and Wilkerson, 2010).

The cost of healthcare is increasing due to preventable problems associated with the system and policy, or lack thereof, which hinders improved outcomes. One example would be when an anesthetized patient has an episode of bradycardia in response to the surgeon manipulating the vagus nerve. In response to that bradycardia the anesthesia provider removes the top from the vial and draws up the atropine. Then, as commonly happens, the surgeon stops manipulating the vagus nerve which causes the patient's heart rate to return back to normal, omitting the need for administration of atropine. The anesthesia provider acted responsibly in response to the bradycardia. However, the fact remains that not only was that patient charged for a drug that they never actually received, but the drug is now wasted after the procedure, which increases the overall cost.

Another example involves a patient who suddenly has a fairly common complication called laryngospasm during extubation. It is imperative that if the spasm cannot be broken with other methods, that paralytic be given in order to ventilate the patient, as in the example previously presented of little Jacobi Hill. This is not the time to have to turn your back on a patient and take minutes to draw up succinylcholine while the patient is de-saturating because their anesthesia provider cannot hold positive pressure due to the fact that they are too busy drawing up medication. It is clear to see how much safer it would be for a patient to be protected by a policy that could foresee issues and prevent ADEs ahead of time and standardized pre-filled syringes for immediate administration.

Review of Related Literature

A systematic literature review was conducted to direct, design, and develop this capstone project using the Agency for Healthcare Research and Quality (AHRQ), the Cumulative Index of Nursing and Allied Health Literature (CINAHL), Cochrane Library, Centers for Medicare and Medicaid Services (CMS), JCAHO, the CDC, the AANA, EBSCO, and other evidence based resources.

The PICO question that guided this literature review and project was: In patients undergoing surgery, who require anesthesia, do vial-filled medication delivery systems potentiate a risk to patient safety, decrease outcomes, increase medication waste, and increase cost of healthcare? A literature review was used to determine if measures were taken to have pre-filled syringes prepared in an anesthesia drug tray, would that result in a safer, more cost-effective practice with less medication errors, less drug delays, and faster turnover.

In 2010, JCAHO released updated labeling criteria to be followed in procedural areas. The 2010 National Patient Safety Goals state that "when a drug is drawn into a syringe or otherwise used from its original container it must be immediately administered. 'Immediate administration' means with no intervening steps or functions prior to administration. [They further outline labeling medications and solutions in the context of NPSG.03.04.01 which state that] the labeling expectation for this safety goal are consistent with the requirements which state that the label must include: The drug name, strength, and amount, expiration date when not used within 24 hours, expiration time if less than 24 hours (which applies to only a few drugs), as well as the date prepared and diluents for all compounded IV admixtures. [In light of these safety goals,

the Joint Commission] approves the purchase and use of pre-filled, pre-labeled syringes such as on procedure trays." (The 2010 National Patient Safety Goals, 2010, pp. 5-6)

The CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care states that "Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids or contaminated equipment" (CDC, 2013, p. 6). This means that medication should be drawn and labeled outside of patient areas, including the operating room. This is virtually never adhered to, and never will be, as long as the anesthesia providers use vials that must be drawn up when conditions mandate their administration. There is an obvious contradiction between the current practice standards and the CDC's guidelines.

"Operating rooms and the perioperative area are the most medication-intensive areas in a hospital. These areas use more medications, especially high-alert medications, than any other unit, but operate with fewer safety measures in place" (Brown, 2014, pp. 466). The Anesthesia Patient Safety Foundation's (APSF) new standard of medication administration includes further safety measures that exceed the standard Joint Commission recommendations of labeling and visual verification of labels. "Pre-filled syringes and standardization of medications, workstations, and technology have been shown to reduce the number of Adverse Drug Events (ADE) by at least 21% and, in certain institutions, by much more than 21%. The available information is sufficient to promote the implementation of pre-filled or premixed syringes in anesthesia departments to reduce the number of ADEs and become compliant with the APSF, Joint Commission, and Institute of Medicine" (Brown, 2014, pp. 465-469).

To provide additional evidence for practice, the APSF states that high alert drugs, such as phenylephrine and epinephrine, used routinely by anesthesia providers, should be available in standardized concentrations and/or diluents prepared by pharmacy in a ready-to-use syringe and should have standardized, fully compliant, machine readable labels. They continue to include that "routine provider-prepared medications should be discontinued whenever possible. Clinical pharmacists should be part of the operating room team, and standardized pre-prepared medication kits by case type should be used whenever possible" (Eichhorn, 2010).

According to the World Health Organization (WHO), applicable legislation is defined as the instrument by which the implementation of a drug policy is given a legal basis by statutorily defining the various strategies for achieving the objectives of the policy. It also defines the qualifications, duties, privileges, and obligations of individuals, organizations, and institutions. "For the effective implementation of legislation, there is a need to review and update the relevant laws regularly, in consultation with relevant stakeholders (such as pharmaceutical companies, anesthesia providers, and surgical patients), in order to achieve the desired objectives. Some of the existing drug laws are in dire need of review and harmonization" (National Drug Policy, 2005, p. 14).

The wave of the future is pre-filled syringes and pre-filled, pre-labeled syringe filled anesthesia drug trays. The American Association of Nurse Anesthetists' AANA News Bulletin (2015) highlighted pre-filled syringes in anesthesia practice. They cited companies, such as PharMEDium, who pay tribute to their specific pre-filled, pre-labeled syringe, which utilize the American Society for Testing and Materials standard for color

differentiation of anesthesia syringe medications, endorsed by the American Society of Anesthesiologists (p. 36).

Differentiating color is a helpful visual differentiating tool but color alone it is not enough to distinguish medications within a class, so the medication name was implemented in six different locations to guarantee the most crucial information is observable from any angle. They further added specific consistent lettering suggested by the Institute for Safe Medication Practices (ISMP), and a variety of visual cues, including shapes and reverse print to create a conspicuous layout proposed to support medication administration in emergency situations. After completing a widespread facility investigation of existing practice and previous medication errors to improve the OR label draft, syringe labels now include drug name on circular rings and vertical stripes alongside graduated inscription, guaranteeing the medication name is visible during drug selection but also through administration when the principal focal point is on the graduated marks (PharMEDium, 2014). Quality improvements include the implementation of sterile, industrially accessible medication in ready-to-use medication syringes.

The European Board of Anesthesiology (EBA) recommendations for safe medication practice state that "all medications need to be prepared for routine use in anesthesia, intensive care, and emergency medicine and pre-filled syringes should be used wherever possible" (EBA recommendations for Safe Medication Practice, 2011 p. 294). Research provided many studies revealing evidence of utilization of pre-filled syringes, especially in an article entitled "Medication Errors during preparation and treatment delays." The objective was to examine medication errors that occurred during

the preparation and administration of medication used in an intensive care unit. The analysis was carried out in a 12-bed ICU and data, were composed over 16 randomly selected days at various medication times. A skilled spectator worked alongside the nurses during medication rounds. Errors were recorded during the inspection period of medication administration and preparation. Drugs most used in the ICU were selected. Information about the method of preparation and administration of the chosen medications were analyzed against a checklist, which was organized using manufacturers' instructions. Out of 524 preparations and administrations, the calculated number of opportunities for error was 4040. Identifiable errors were 380/4040, (9.4%), and of those, 33.6% were associated to the preparation process and 66.4% with the administration process.

Clinically relevant outcomes were assessed, and the risk and benefits of the treatment were noted, and while it is clear that medication errors would be reduced and treatment delays improved, this method would have considerable monetary implications for healthcare providers. Further research is needed in the area of cost effectiveness. Lastly, the expectation is safe, effective, first-rate treatment. "Providing infusions in pre-filled syringes would reduce medication errors and treatment delays, improve patient safety, and effectively meet these expectations" (Fahimi et al., 2008, p. 104).

According to Dr. Stratman, lead researcher from Barnes-Jewish Hospital, "the use of pre-filled, pre-labeled syringes likely will be cost neutral to the hospital, with the costs of outsourcing medications offset by the savings in otherwise wasted drugs. But when you look at the impact of the initiative on quality and safety for the patients … it's what's right to do even if it costs a little more" (Blum, 2013, p. 3).

Further incidence of medication errors and treatment delays were directly evaluated in a study analyzing errors during the preparation of medication. The background considered the degree and regularity of errors and treatment delays made as a result of bedside preparation, instead of using pre-filled syringes. Forty-eight ICU nurses volunteered in this randomized, blinded, controlled study carried out in a metropolitan hospital. Medications were drawn from concentrated vials, or they were provided in pre-filled syringes beforehand.

They compared both preparation time and concentration of the medication against medication prepared by pharmacists. It took nurses 156 seconds to initiate infusions when using pre-filled syringes compared with 276 seconds when preparing them from vials, averaging a delay of 106 seconds. When using pre-filled syringes, medication errors were 17 times less likely and they resulted in a reduction of medication errors and treatment delays while simultaneously improving patient safety (Adapa et al., 2012).

The pre-labeled syringes saved money and time, and increased patient safety. The review supports the need for further study in order to determine each locations specific monetary value of medication errors. The results will help providers care for patients as patient safety and safe medication administration can directly be applied into clinical practice. Standard medication labels should be available to the provider to improve patient safety (Adapa et al., 2012).

In a letter written by a group of notable anesthesia providers, ranging from noted authors, CRNAs, and MDAs, there were a list of recommendations and requested revisions made to the JCAHO written requirements. They stated that they had exceptional concerns with exclusion on pre-labeled syringes, identification of spinal and epidural

medication via labeling, and the label authentication requirements when two providers are involved. They gave specific reasons for their requests, and it was clear, based on their argument, that changes needed to be made to the JCAHO recommendations and requirements. The overturning of policies and procedures as outlined improves patient safety and efficiency of practice (Santoro, Stoelting, Wagner, & Warner, 2010).

A study in an OB unit in France examined the use of ephedrine pre-filled syringes and concluded, with valid evidence, that they did indeed reduced anesthesia costs. It evaluated the utilization, expense, and consumption of ephedrine against the use of ephedrine via pre-filled syringes. The expense included vials and consumable equipment against pre-filled syringes and results were evaluated on the base of cost. Over one hundred parturients were evaluated in the study. They found that 155 vials were used for verses 45 pre-filled syringes. The outcomes of the study demonstrate that the use of pre-filled syringes considerably reduced medication waste and decreased cost in OB anesthesia. The results showed that the use of pre-filled syringes significantly reduced the wastage of ephedrine, allowing subsequent cost minimization in obstetrical anesthesia (Bellefleur et al., 2009). If it were possible to ensure that the pre-filled syringes were used for "immediately for bradycardias… then the pre-filled syringes [would] save money" (De Mello & Vipond, 2000 p. 303).

In conclusion, The U.S. National Library of Medicine states that in 2008 the annual cost of measurable medical errors that harm patients was $17.1 billion and the second most common medication error is dilutional drug errors (U.S. National Library of Medicine National Institute of Health, 2011).

A new policy in favor of standardization of pre-filled syringes and pre-filled anesthesia drug trays would significantly reduce medication waste and decrease cost. By simply changing the policy on the delivery system, and nothing else about a given providers practice, cost is decreased, medication waste among anesthesia providers becomes significantly decreased, patient safety is enhanced, induction time is decreased, and the providers job is more streamlined.

CHAPTER II

METHODOLOGY

Design and Target Population

In establishing a comprehensive cost benefit analysis, comparing a sample pre-filled anesthesia drug tray against a vial-filled drug tray, recommendations, standards, and guidelines were compiled to show a shift toward pre-filled, pre-labeled syringes. In 2010, JCAHO released updated labeling criteria to be followed in procedural areas. In an effort to comply with The 2010 National Patient Safety Goals, "when a drug is drawn into a syringe or otherwise used from its original container it must be immediately administered with no intervening steps or functions prior to administration" (The 2010 National Patient Safety Goals, 2010, p. 5). They further outline labeling medications and solutions in the context of NPSG.03.04.01 which states that "the labeling expectation for this safety goal are consistent with the requirements which state that the label must include: The drug name, strength, and amount, expiration date when not used within 24 hours, expiration time if less than 24 hours, which applies to only a few drugs, as well as the date prepared and diluent for all compounded IV admixtures". In light of these safety goals, JCAHO promotes the purchase and use of pre-filled, pre-labeled syringes such as on procedure trays (The 2010 National Patient Safety Goals, 2010).

As previously stated, the CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care state that "Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids or contaminated equipment" (CDC, 2013, p. 6). Therefore, medication should be drawn and labeled outside of patient areas, including the operating room.

According to the AANA (2014), "operating rooms and the perioperative area are the most medication-intensive areas in a hospital. These areas use more medications, especially high-alert medications, than any other unit, but operate with fewer safety measures in place" (p. 465). The APSF new model of medication administration includes further protection to surpass the JCAHO recommendations of labeling. "Pre-filled syringes and standardization of medications, workstations, and technology have been shown to reduce the number of ADEs by at least 21% and, in certain institutions, by much more than 21%. The available information promotes the implementation of pre-filled syringes in anesthesia departments to reduce the number of ADEs and become compliant with the APSF, the Joint Commission, and Institute of Medicine" (Brown, 2014, pp. 465-469).

Detailed Procedures

In an effort to meet the various recommendations and guidelines, an initial baseline was established to include a set of specific medications, with specific dilutions, labels, and quantity of each. A list of 37 anesthesia drugs, used by various facilities throughout Mississippi, was formulated. Next, a comprehensive analysis compared the current vial-filled medication administration of a regional medical center in south Mississippi against pre-filled syringes. The specific dilution of each medication, the concentration of each vial, and the cost of each medication were identified. Specific variables were compared to offer the most cost-effective option for this specific facility. Specific information gathered included a description of the most frequently used medications, vial cost, cost of preparation and supplies such as blunt needles and empty

syringes, and monthly volume of specific medication administration (See Appendices A and B).

Setting and Evaluation

Once this information was compiled at a facility in south Mississippi, recommendations were made to change only what would benefit the facility. For example, if a particular medication was rarely used or if the pre-filled medication might expire before the providers thought they would be able to administer the syringe, that syringe was not recommended for change from vial to syringe. The analysis included all commonly administered anesthetic medication against pre-filled syringe availability, cost, and expiration. A list of medications was compiled in a cost benefit analysis and a medication tray provided to ensure that medications were always in the same location to ensure safety and to streamline delivery. For example, the provider knows, almost without having to think about it, that the Rocuronium is always located in the top right corner, red in color, in a 5ml syringe at a dilution of 10 mg/ml. This way, no matter which OR the provider practices in, the medication is the same every time. The direct cost was compared between each vial and the counterpart syringe. Final calculations were made and revealed significant decrease in cost of both individual pre-filled syringes and the finalized anesthesia drug tray. These findings, however, represented only the direct cost. Further substantial financial savings were identified to include indirect cost benefit of pre-filled syringes. Lastly, providers were interviewed to discuss the positive and negative aspects of pre-filled syringes, and potential room for improvement. Feedback was then taken from the providers, and all of the paralytics were changed to vary in color instead of all being red in color, following the recommendations of the

providers. This was the only notable recommendation from the providers. These data were utilized in the results section for the Business Plan.

Table 1

The Essentials of Doctoral Education for Advanced Nursing Practice

DNP Essential	Fulfillment of DNP Essential
I	The specific scientific underpinnings for practice: The benefits to the practice of anesthesia are evident in the direct and indirect cost benefit analysis. The research shows that pre-filled syringes increase safety, decrease medication waste, and is more cost-effective than vials. Furthermore, regulations and recommendations of governing bodies encourage automated dispensing systems and pre-filled syringes in the future.
II	Organizational and systems leadership for quality improvement and systems thinking: Quality improvement measures were utilized in multiple research articles, and prove that pre-filled syringes, when implemented, improve quality and safety while decreasing the cost of healthcare by significantly decreasing drug waste and dilutional medication errors.
III	Clinical scholarship and analytical methods for evidence-based Practice: Despite the need for further quantifiable research, the implications of existing 17.1 billion dollar medication errors were used to show obvious results of the analysis.
IV	Information Systems/Technology: Patient Care Technology for the cost benefit analysis shows that by simply changing nothing more than the packaging technology used to deliver medication multiple systems are significantly improved.

Table 1 (continued).

DNP Essential	Implications for Pre-filled syringes
V	Improvement and Transformation of Health Care: The implementation of pre-filled syringes offer the promise of transforming and improving health care via improved quality and safety and decreased cost of healthcare in the areas of significant decrease of drug waste and dilutional medication errors.
VI	Health Care Policy for Advocacy in Health Care: Evidence showing pre-filled syringes' ability to improve healthcare provides the foundation for unassailable advocacy for improved outcomes, which should be the basis of health care policy
VII	Interprofessional Collaboration for Improving Patient and Population Health Outcomes: In order to successfully coordinate a comprehensive cost benefit analysis to improve outcomes, interprofessional collaboration is essential
VIII	Clinical Prevention and Population Health for Improving the Nation's Health: Pre-filled syringe implementation dramatically drive the cost of the nation's health care down and clearly prevent costly medication errors while simultaneously improving ease of practice for anesthesia providers

CHAPTER III

RESULTS

Reliance Pharmaceuticals & Consulting Business Plan

Based on the research that shows the superiority of pre-filled syringes, reliance Pharmaceuticals was created to bridge the gap between the research and clinical practice. Reliance Pharmaceuticals is a company that manufactures customizable pre-packaged drug trays or other drug delivery systems and consults for drug delivery systems. We have a compounding pharmacy under contract to draw up and pre-package syringes, specifically organized for anesthesia providers' unique needs based on their drug usage, setup, and dispensing system.

Mission

Our Mission is to provide superior products for superior outcomes. We aim to make available superior pharmaceutical products with improved value to anesthesia providers and other users, advancing patient care and improving the quality of anesthesia and healthcare. Our goal is to be the nation's largest privately held and one of the fastest growing distributors of pre-filled syringes in the United States. Our focus is serving hospitals, surgery centers, physician offices and other health care markets.

Objectives

Our objectives are to be fully founded by October 2015, reach 7 contracts locally, followed by a spread of contracts in the state of Mississippi, followed by contracts regionally, and ultimately nationally. Customer satisfaction is at the cornerstone of our business and is measured by anesthesia surveys, return customers, and increased sales. We endeavor to guide our profession with the most cost-effective medication and

invaluable clinical solutions for anesthesia providers and their patients, while advancing superiority and efficacy in each part of our process.

This is a growing industry, starting locally and working toward national distribution. Short-term goals include moving from vial-filled trays to pre-filled syringe trays, while long-term goals are standardization of pre-filled syringe drug trays within the operating room. Such standardization will thus augment our sales. Strengths include providing an opportunity to increase operating room turnover rates and decrease medication related errors and infections, and decrease drug administration delays. Recommendations from the CDC and Joint Commission further strengthen our overall goal toward safer, more streamlined practice. Once implemented, hospitals and anesthesia providers will see the benefit of pre-filled syringes first hand. As anesthesia providers ourselves, we have experienced the lag time of having to gather and prepare medications between cases. We bring this experience and understand the urgency in emergency situations.

Our goal is to become a Limited Liability Corporation. We have selected this form because we blend elements of partnership and corporate structures. Partnerships are between compounding companies and anesthesia providers. We blend the corporate structure of CEO, CFO, VP of sales and marketing, and VP of public relations with the partnerships between compounding pharmacies and anesthesia provider.

Guidelines, Standards, and Recommendations

In 2010, the JCAHO released updated labeling criteria to be followed in procedural areas. In an effort to comply with The 2010 National Patient Safety Goals, "when a drug is drawn into a syringe or otherwise used from its original container it must

be immediately administered with no intervening steps or functions prior to administration" (The 2010 National Patient Safety Goals, 2010, p. 5). They further outline labeling medications and solutions in the context of NPSG.03.04.01 which state that "the labeling expectation for this safety goal are consistent with the requirements which state that the label must include: The drug name, strength, and amount, expiration date when not used within 24 hours, expiration time if less than 24 hours (which applies to only a few drugs), as well as the date prepared and diluent for all compounded IV admixtures". In light of these safety goals, the JCAHO approves the purchase and use of pre-filled, pre-labeled syringes such as on procedure trays. (The 2010 National Patient Safety Goals, 2010).

The CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care state that "Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids or contaminated equipment" (CDC, 2013, p. 6). This means that medication should be drawn and labeled outside of patient areas, which would include the operating room.

According to the AANA (2014), "Operating rooms and the perioperative area are the most medication-intensive areas in a hospital. These areas use more medications, especially high-alert medications, than any other unit, but operate with fewer safety measures in place" (p. 465). APSF new model of medication administration includes further protection to surpass the regular JCAHO recommendations of labeling. "Pre-filled syringes and standardization of medications, workstations, and technology have been shown to reduce the number of Adverse Drug Events (ADE) by at least 21% and, in certain institutions, by much more than 21%. The available information is sufficient to

promote the implementation of pre-filled or premixed syringes in anesthesia departments to reduce the number of ADEs and become compliant with the APSF, Joint Commission, and Institute of Medicine" (Brown, 2014, pp. 465-469).

High alert drugs, such as phenylephrine and epinephrine, should be available in standardized concentrations/diluents prepared by pharmacy in a ready-to-use (bolus or infusion) form and ready-to-use syringes and infusions should have standardized fully compliant machine– readable labels. Furthermore, "Routine provider-prepared medications should be discontinued whenever possible. Clinical pharmacists should be part of the perioperative/operating room team, and standardized pre-prepared medication kits by case type should be used whenever possible" (Eichhorn, 2010, p. 25).

Products and Services

Our product involves a consolidation of commonly used, and some uncommonly used, medications in shrink-wrapped, pre-filled syringes in a cut-foam insert within a plastic tray and/or pre-filled syringes in automated delivery systems such as Pyxis or Omnicell. We will have our syringes pre-filled and prepared at our contracted compounding pharmacy that will guarantee the expiration dates and the highest quality compounding and sterilely in our prepared syringes. Per the CDC and JCAHO guidelines, our trays will have pre-filled and pre-labeled syringes that bypass human error and improve safety and efficacy of the anesthetic process and thus significantly decrease medication errors, drug waste, and response time during emergency situations, while increasing room turnover rates, and continuity of care.

Reliance Pharmaceuticals four key areas of Service

1. Assessment:

Reliance Pharmaceuticals' dedicated operating room specialists are trained to help assess your individual needs. Each consultation will include a confidential detailed observation report to help you evaluate drug usage and waste. Evaluations of medication usage are utilized to support implementation of pre-filled syringes based on the hospital's goals for improving medication safety and process efficiencies. The assessment ensures an improved compliance among The JCAHO as it pertains to labeling and USP 797.

2. Development:

The Reliance operating room specialist will include input from both pharmacy and anesthesia to develop custom medication tray layouts to support a comprehensive solution.

3. Maintenance:

The Reliance operating room specialist will provide ongoing support to ensure optimal integration.

4. Implementation:

Reliance specialists will assist with every step of the implementation process to support a smooth safe and efficient process. A detailed implementation timeline is provided to help ensure a seamless transition to Reliance ready-to-use services.

Benefits:

1. Seamless Integration:

The dedicated Reliance operating room specialist will provide you with a customized solution that meets pharmacy and anesthesia requirements.

They will assist you through every step of the process to ensure a smooth transition to ready-to-use medications.

2. Compatible Storage Solutions:

Reliance's ready-to-use syringes are compatible with medication trays designed for anesthesia carts, as well as the most commonly used automated dispensing cabinets, including mini-drawers for controlled substances.

2. Evaluation:

The confidential consultation will help identify opportunities to reduce drug waste and determine which Reliance preparations offer the best overall value for your needs.

3. Standardized Drug Tray Design:

Medication trays in various colors can be used to further differentiate the specialty trays from the general surgery trays.

Marketing Plan and Economics

In order to succeed, effective marketing and branding are essential. This begins with vigilant, methodical investigation. It is precarious to take for granted that our company already knows about our anticipated market. Significant market research was gathered and primary as well as secondary marketing research was utilized. Data collection were procured from the Cochrane Library, CINAHL, MEDLINE, governing anesthesia entities, professional associations and professional publications provided industry-specific data, and local hospital demographics were critical in defining the local market. Specific methodologies outlined comparison between current trends and proposed changes. Information was packaged for presentation to key stakeholders and decision makers at each given facility.

Our initial market consists of seven locations within the greater Hattiesburg area including Forrest General Hospital, Larry A. Woodall, Orthopedic Institute, Southern Bone and Joint, Wesley Medical Center, Hattiesburg Eye Clinic, and Southern Anesthesia. In addition to the initial seven facilities, five other facilities will provide opportunity for growth including ambulatory surgery centers, plastic surgery centers, Hattiesburg GI associates, and Southern Eye Center.

Table 2

Variable Shipping Costs

Facility	Variable number of drug trays used daily
Forrest General Hospital	50
Larry A. Woodall	25
Orthopedic Institute	25
Southern Bone and Joint	25
Wesley Medical Center	50
Hattiesburg Eye Clinic	25
Southern Anesthesia	50

Reliance Variable Profit: 205 Trays (daily): Cost and Profit breakdown: $0.50 per medication, $5-15 dollars per tray, average 205 cases daily for all accounts equals $2,050 daily, multiplied x 7 days a week is $14,350 per week, multiplied x 52 weeks in a year = $746,200 annually. A $0.05 discount per syringe to Reliance is negotiated from contracting compounding pharmacy. (NOTE: not all drugs from every tray will be used for any given case, therefore Reliance profit is variable depending on any given surgical case)

Reliance has 7 out of 11 facilities offering surgical services within the greater Hattiesburg area. This yields a 58% market share. Prior to standardization of pre-filled syringes (our long term goal), there is an undetermined demand, however, our goal is to create a high demand where there is none now. Current trend is vial use from pre-packaged anesthesia drug trays in which the provider prepares each medication individually as needed. Unfortunately this, more often than not, is done is such a way to violate the guidelines and recommendations set by the governing entities. Pre-filled syringes are used in O.B suites and trauma suites but there are no pre-packaged drug trays with pre-filled syringes at these locations currently. Our goal is to secure local facility contracts and then grow statewide, regionally, nationally, and eventually standardize pre-filled syringes, where we will already have the majority of the market share. Potential barriers include contract negotiations, future competition, and adequate patenting.

Table 3

Capital costs and Startup expenses

Factor	Monthly Cost
Furnished Office building deposit	$2000
Utilities deposit (electric, sewage, internet, water, phone)	$500
Webpage setup	$500
Travel Expenses $2,795(gas), $400 (food)	$3195
Rent	$1000
Attorney fee (annually) / contracts, etc. $250/hr x 2 hrs each x 6 occasions: $1500 + LLC (annually) $800 = $2300	$192

Table 3 (continued).

Factor	Monthly Cost
CPA (Monthly)	$500
Webpage maintenance	$200
Patent on pre-filled drug tray (one-time fee)	$500 - $10,000

To avoid potential financial barriers, high costs of both drugs and shipping will be transferred to the hospital or surgery center, who can then transfer the cost to each patient once drugs are used (Reliance system helps ensure that all charges are captured to facilitate this transfer.) Specific cost analysis is outlined (Appendix A). To address potential barriers associated with patenting our product, wholesale prices are negotiated and order in bulk to reduce cost to the healthcare facility. This would prevent the provider from ordering directly from our wholesaler. If the government standardizes pre-filled syringes, a monopoly would exist on anesthesia drug trays in our local market. If the economy suffers, hospitals might be prone to cut costs, including seeking out the cheapest (not necessarily the best or safest) drug options. Hopefully, standards, guidelines, and recommendations will bring about standardization and such change will bring about pre-filled syringe standardization.

Contracts are to be extended three to six months based upon the need of each individual facility. Warranty, refund, and quality responsibility are transferred to the manufacturer/compound pharmacy who guarantees the quality of their dilution, labeling, measurement, life expectancy and sterility. Shipment will be handled directly by the

compounding pharmacy. Our initial market consists of 7 locations within the greater Hattiesburg area including Forrest General Hospital, Larry A. Woodall, Orthopedic Institute, Southern Bone and Joint, Wesley Medical Center, Hattiesburg Eye Clinic, and Southern Anesthesia.

Our competition would be drug tray distribution companies who distribute filled vials instead of filled syringes. Other competition would be drug dispensing system companies such as Pyxis and Omnicel.

They will be competitive in cost and they also have the market now. Our biggest challenge will be getting the decision makers to choose our drug trays.

Table 4

Competitive Analysis Table

Factor	Reliance	Strengths	Weaknesses	Competitor A	Competitor B
Products	Superior	Compliant Safety, $, Labels, Dilution, Speed	Expensive	Vials	Pre-labed, Pre-filled, Pre-packaged
Price	Variable	Saves $ - med errors / turn-over time	More expensive initially	Variable	Variable
Quality	Superior	Same as less effective competitor	N/A	N/A	N/A

Table 4 (continued).

Factor	Reliance	Strengths	Weaknesses	Competitor A	Competitor B
Appearance	Pre-filled immediately available	Immediate available	N/A	Familiar vials	Pre-filled immediately available
Sales Method	Direct B2B sales	Personal	Potential loss of business	Equal	Equal
Advertising	Direct B2B	Personal / Reliable	Less popular	Nation Wide commercials	Trusted, reliable, familiar
Image	Equal	Equal, Compliant	N/A	Vials – familiar	Equal
Selection	Equal	Equal	Equal	Equal	Equal
Stability	Equal as long as they used the vial correctly	Equal	Equal	Equal	Equal
Expertise	Equal	Equal	Equal	Equal	Equal
Reputation	Weakness, must establish a reputation	New and Evidence Based	New and unknown	Known, respected, trusted	Bright Future (EBP)

Our niche corner of the market is a pre-filled, pre-labeled, pre-packaged anesthesia drug tray. Pre-filled pre-labeled syringes cut down on costly medication errors, decreased contamination, due to their being drawn under a sterility hood,

decreased draw-up time, and decreased room turnover time. This enables us to have the market share of competition in our targeted area with the ability to expand statewide, regionally and nationally with ultimate standardization of our product, which will give us a monopoly on the market. Our marketing strategy will be targeted, marketed, scheduled presentations at local facilities.

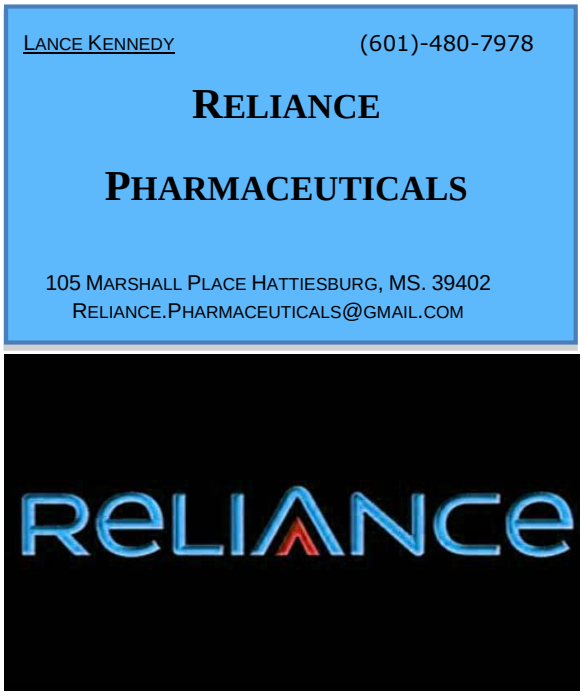

Figure 1. Business Card Design with bright blue and black color scheme to augment the operational plan and promotion

All syringes will be pre-packaged via contracted compounding pharmacy. Quality is guaranteed via individual compounding pharmacy that prepare the syringes under sterile, hooded conditions. Customer service will include and ensure that each facility has adequate supply, ability to replace damaged syringes, and an open line of communication for questions/comments and restock requests. Monthly and weekly medication usage statistics for each drug will be requested from each facility and will be

coupled with specific short-term inventory requests. The amount of space needed will be minimal. Trays will be completed per order due to expiration constraints. No building will be needed for medication tray storage, as they will be shipped directly from compounder to facility. Business hours will be Monday through Friday from 8am to 5pm with 1 person on call 24 hours a day, 7 days a week including holidays, should an emergency surface.

Permit to dispense and distribute medications. This is placed in the hands of the compounding pharmacy. Medication control, dispensing and distributing are regulated and records of each medication and amount must be recorded and filed. Liability insurance will include $6000/year per million dollars of coverage. Trademarks associated with completed anesthesia trays are still pending. Medical professionals, specifically CRNAs, will be employed upon expansion. As the business grows, employees will be interviewed with a minimum requirement being a CRNA with adequate business experience. Original employees (4) will negotiate an equal salary pay rate with additional payment for call schedule and overtime. On-the-job training will be needed for new hires after a day of classroom time to cover basic protocol, substance abuse training, and specific job requirements.

The beginning schedule will be all employees 8am-5pm Monday through Friday with an on-call rotation including but not limited to: professional communication with compounding pharmacy and health care facility, mediate sales and consulting and acquire new business, process medication orders, must function in strict accordance with standard, written procedures and guidelines with deviation approved by owner.

Seasonal buildups are negligible since orders will be processed and produced upon order request, and medications expire and lead-time will depend on the supply in need and the current order load. Processing can be sent to an outlying compounding pharmacy if the current pharmacy load is exceeded. Multiple compounding pharmacies are contracted to avoid drug shortages and existing customers get priority in the event of such drug shortages. Inventory furnished will be split evenly between compounding pharmacies.

Contracted Compounding Pharmacies include Advantage Compounders located at 6375 U.S. Highway 98 West Suite 40 & 50 Hattiesburg, MS 39402 and Vital Care Compounders located at 115 South 40th Avenue Hattiesburg, MS 39402. Delivery will be arranged by our company to pick up the product and deliver it directly to the health care facility. Sale is complete upon full payment of each order. Reliance Pharmaceuticals retains their $0.50 per drug and remaining payment goes directly to compounding pharmacy for order preparation. Credit will be used only if absolutely necessary and must be approved by the owner. The creditworthiness of the healthcare facilities will be determined by history of sales to that particular facility and remain at the owners discretion. New accounts mandate initial full payment and where future credit options are allowed, payment will be due within 30 days of product delivery. If late payment is expected, a phone call is to be made within 30 days. A letter will be sent when 7 days past due and at 30 days past due, attorneys will begin issuing letters.

Management and Organization

The three initial partners and investors will be responsible for managing specified daily business as agreed upon via owner and final decisions are to filter through owner.

As Certified Registered Nurse Anesthetists, each partner will bring to the business an understanding of the drugs used, clinical experience of how efficient and effective our product is, and how well it will benefit the facility that purchases. In the event of conflict among partners, owner retains final and ultimate authority. No loans will be applied for, as initial startup costs are invested via owner and three partners/investors.

Table 5

Professional Advisory and Support

Service	Name
Owner	Lance Kennedy
Board of Directors	Lance Kennedy, Sayha Ma, Chris Turner, Jarrod Fontenelle
Management Advisory Board	Patsy Anderson, Vicky Stuart, Bonnie Harbaugh
Attorney	Jack Denton Law office PLLC
Accountant	James McDonnell, CPA
Insurance agent	Lance Ware (State Farm)
Banker	Wells Fargo
Consultants, Mentors, and key advisors	Board of Directors and Advisory Board

CHAPTER IV

SUMMARY

The future of Anesthesia drug delivery is obvious, and, the data provide clearly defined recommendations and guidelines. The research reveals overwhelming evidence that the use pre-filled syringes would reduce medication errors and treatment delays and improves patient safety outcomes (Fahimi et al., 2008). "When you look at the impact of Pre-filled syringes and their impact on quality and safety for the patients, it's what's right to do even if it costs a little more" (Blum, 2013, p. 3). Also, when using pre-filled syringes, medication errors are 17 times less likely and would reduce medication errors and treatment delays, and improve patient safety (Adapa et al., 2012). Pre-filled syringes reduce significantly the wastage of medication, allowing subsequent cost minimization in anesthesia (Bellefleur et al., 2009).

Summary of Findings

The U.S. National Library of Medicine states that in 2008, the annual cost of measurable medical errors that harm patients was $17.1 billion, and the second most common medication error was dilutional drug errors (U.S. National library of Medicine National Institute of Health, 2011). Additionally, the implementation of pre-filled syringes stands to decrease the cost of healthcare by $420,000,000 annually just from the 21% decrease in Adverse Drug Events (Brown, 2014, pp. 465-469). If it were possible to ensure that the pre-filled syringes were used, then the pre-filled syringes [would] save money (De Mello & Vipond, 2002, p. 303).

To reiterate, the 2010 National Patient Safety Goals state that "when a drug is drawn into a syringe or otherwise used from its original container it must be immediately

administered with no intervening steps or functions prior to administration" (The 2010 National Patient Safety Goals, 2010, p. 5). This makes pre-filled syringes an obvious choice. As well, the CDC's minimum expectations for safe care are that injections are prepared outside of patient areas, which would include the operating room and as such, pre-filled syringes are, again, the obvious solution (CDC, 2013). Furthermore, according to the AANA (2014), "the available information is sufficient to promote the implementation of pre-filled or premixed syringes in anesthesia departments to reduce the number of adverse drug events and become compliant with the Joint Commission, and Institute of Medicine" (Brown, 2014, pp. 465-469). It seems to be only a matter of time before each individual operating room will be required to have its own automated drug dispensing system or pre-filled drug tray.

Current policies on Drug storage simply mandate that an entity reasonably show that they are adhering to vague medication storage standards. Anesthesia drug policy, storage, and distribution are decided on by each individual facility with minimal attention to detail. If current healthcare policy would ensure the use of pre-filled syringes, their standardization would immediately begin to improve outcomes and healthcare cost would be immediately decreased.

In the OR, precision and split second decisions are essential to the quality of patient care. Instead of relying on vague policy options to steer the quality of anesthesia, policy should be created where pre-filled syringes are utilized with pharmacy prepared labels that are intended to augment medication name identification during potentially grave circumstances. Further recommendation values policies that included standardized color differentiation, easy to read labels with graduated markings, dilution, and expiration

dates that would increase quality, speed and efficiency, and dramatically reduce drug waste.

Implications for Nursing Practice

Reliance Pharmaceuticals specializes in pre-filled, pre-labeled, and prepackaged syringes and consulting. They show how to save the contracting facility approximately one million dollars per year and how to significantly decrease dilutional drug errors, drug wastage, and ADEs from an anesthetic point of view. Let's take a look at how we do this. Dilutional errors are the second most costly medication errors. Although this may be true, there is room for improvement. The national average of these errors are $21 billion dollars per year. Mississippi's average of medication errors is $420 million dollars. The estimated per hospital medication errors equal $3.5 million dollars. Twenty-three percent of dilutional errors come to the average of $805,000 dollars. In addition to dilutional errors, average drug wastes for the surrounding hospitals are $42,000 a year. The total savings for increased room turnover, based on research is: 1.85 minutes per case. The average case count in a day of the projected initial hospital contract caseload is 53 cases a day. In an effort to use conservative, realistic numbers if 50 cases a day times 1.5 minutes = 75 minutes a day, 75 minutes times 7 days a week = 525 minutes. 525 minutes times 52 weeks in a year = 27,300 minutes = 455 hours 11.375 work weeks you will get about three months back which equals up to $70/hour x 455 hours = $31,850.

The cost of an anesthesia tray of vials is $313 dollars. The time to administer a pre-filled syringed drug is 13 seconds, whereas it takes 35 seconds to administer a vial drug. How much money is our business making? Initially, $0.50 per medication, $5-15 dollars per tray, average 205 cases daily for all accounts, $2,050 daily x 7 days a week

$14,350 per week x 52 weeks in a year = $746,200 annually. Our compounding pharmacy pitch: 205 cases daily x seven days a week = 1,435 cases a week x 52 weeks in a year = 74,620 cases a year (less unused, redistributed medications). $13,431,600 per year is paid to the compounding pharmacy.

Conclusion

The dynamic practice of anesthesia necessitates relentless assessment to generate safeguards. While modification is not always essential, evaluating an organization and looking for cost-effectiveness and improved patient care measures can be advantageous in treatment of illness, in the facility, and in the entire profession of anesthesia. Standardization provides consistency and a universal system, which improves patient safety and can lead to departmental cost savings. In the mission to continually improve our practice and patient care during anesthesia, let us hold diligently to the guiding principles that catapulted our profession to where it is today. This continued approach should lead us to a standardization of pre-filled, pre-labeled syringes in prepackaged drug trays customized to the individual needs of a given facility. The ability to put aside selfish ambition and strive for the greater good will highlight the principles of delaying gratification, character, integrity, and dedication to success that has bought and will continue to bring out the very best in us, as anesthesia providers, and in healthcare throughout the nation.

APPENDIX A

MEDICATION EVALUATION TABLE

Description	Vial Cost	Preparation Supplies	Total Preparation Cost	Current Monthly Volume	Current Monthly Cost	Estimated Monthly Usage post Syringe Implementation	Pre-filled Syringe Price	Monthly cost for Pre-filled Syringe	Financial Difference
Phenylephrine	$4.50	$0.50	$5.00	66	$330.00	40	$4.81	$192.40	-$137.60
Ephedrine	$10.19	$0.50	$10.69	76	$812.44	46	$12.78	$587.88	-$224.56
Vecuronium	$5.45	$0.50	$5.95	54	$321.30	69	$14.99	$1,034.31	$713.01
Cisatracurium	$13.76	$0.50	$14.26	61	$869.86			$0.00	-$869.86
Rocuronium	$8.19	$0.50	$8.69	51	$443.19	31	$8.62	$267.22	-$175.97
Neostigmine	$89.18	$0.50	$89.68	73	$6,546.64	44	$11.30	$497.20	-$6,049.44
Glycopyrrolate	$25.87	$0.50	$26.37	92	$2,426.04	55	$30.81	$1,694.55	-$731.49
Lidocaine	$1.28	$0.50	$1.78	704	$1,253.12	422	$3.83	$1,616.26	$363.14
Epinephrine	$1.18	$0.50	$1.68	13	$21.84	8	$5.38	$43.04	$21.20
Midazolam	$1.37	$0.50	$1.87	186	$347.82	186	$4.52	$840.72	$492.90
Impact							Total monthly impact		-$6,598.67
Annual Impact							ANNUAL Impact		-$79,184.04

APPENDIX B

PHARMEDIUM SAMPLE LABELING TABLE

	DRUG CLASS[A]	EXAMPLES	PANTONE COLOR (unearned)	LABEL EXAMPLES
1	Induction Agents	Etomidate, Ketamine, Methohexital, Propofol, Thiamylal, Thiopental	YELLOW	PROPofol_____mg/mL Date _____Time_____Int_____
2	Benzodiazepines	Diazepam, Midazolam	ORANGE 151	MIDAZolam_____mg/mL Date _____Time_____Int_____
3	Benzodiazepine Receptor Antagonist	Flumazenil	ORANGE 151 AND WHITE DIAGONAL STRIPES	FLUMAZenil_____mg/mL Date _____Time_____Int_____
4a	Muscle Relaxants (Depolarizer)	Succinylcholine[B]	FLUORESCENT RED 805	SUCCINYLcholine_____mg/mL Date _____Time_____Int_____
4b	(Non-Depolarizer]	Atracurium, Cisatracurium, Mivacurium, Pancuronium, Rocuronium, Vecuronium	FLUORESCENT RED 805	ROCURonium_____mg/mL Date _____Time_____Int_____
5	Relaxant Antagonist (Non-Depolarizer)	Endrophonium, Neostigmine, Pyridostigmine	FLUORESCENT RED 805 AND WHITE DIAGONAL STRIPES	NEOstigmine_____mg/mL Date _____Time_____Int_____
6	Narcotics	Alfentanil, Fentanyl, Hydromorphone, Meperidine, Morphine, Sufentanil, Remifentanil	BLUE 297	FENtanyl_____mcg/mL Date _____Time_____Int_____
7	Narcotic Antagonists	Levallorphan, Naloxone	BLUE 297 AND WHITE DIAGONAL STRIPES	NARcan_____mg/mL Date _____Time_____Int_____
8	Major Tranquilizers	Chlorpromazine, Droperidol	SALMON 156	DROperidol_____mg/mL Date _____Time_____Int_____
9a	Vasopressors	Ephedrine, Norepinephrine, Phenylephrine	VIOLET 256	EPHEDrine_____mg/mL Date _____Time_____Int_____
9b	Vasopressors	Epinephrine[B]	VIOLET 256	EPINEPHrine_____mcg/mL Date _____Time_____Int_____
10	Hypotensive Agents	Hydralazine, Nitroglycerine, Nitroprusside, Phentolamine, Trimethaphan	VIOLET 256 AND WHITE DIAGONAL STRIPES	NITROglycerine_____mg/mL Date _____Time_____Int_____
11	Local Anesthetics	Bupivacaine, Chloroprocaine, Lidocaine, Mepivacaine, Procaine, Ropivacaine, Tetracaine	GRAY 401	LIDOcaine_____mg/mL Date _____Time_____Int_____
12	Anticholinergic Agents	Atropine, Glycopyrrolate, Scopolamine	GREEN 367	GLYCOpyrrolate_____mg/mL Date _____Time_____Int_____
13	Beta Blockers	Esmolol,[B] Labetolol,[B] Metoprolol[B]	COPPER 876U	LABETalol_____mg/mL Date _____Time_____Int_____

APPENDIX C

THE UNIVERSITY OF SOUTHERN MISSISSIPPI IRB APPROVAL

THE UNIVERSITY OF
SOUTHERN MISSISSIPPI

COLLEGE OF NURSING
Systems Leadership & Health Outcomes Department
118 College Drive #5095 | Hattiesburg, MS 39406-0001
Phone: 601.266.5462 | Fax: 601.266.5927 | nursing@usm.edu | www.usm.edu/nursing

July 29, 2015

To Whom It May Concern:

The doctoral capstone project submitted to IRB by Lance Kennedy has been reviewed by Bonnie Harbaugh, PhD, RN, who is a College of Nursing representative of The University of Southern Mississippi Institutional Review Board. The project is a business/policy analysis that does not involve human subjects. Since the capstone project does not use human subjects, this project does not require IRB Approval.

In this doctoral capstone project proper protection of organizational data will be adhered to by Mr. Kennedy and his advisor, Dr. Patsy Anderson. If Mr. Kennedy's project changes to include Human Subjects, he will notify his doctoral capstone advisor, and apply for IRB approval.

Sincerely,

Bonnie Lee Harbaugh

Bonnie Lee Harbaugh, PhD, RN
USM IRB Member
College of Nursing Representative

Professor and Chair
Department of Systems Leadership and Health Outcomes
College of Nursing
The University of Southern Mississippi
Bonnie.Harbaugh@usm.edu
601-266-5250

APPENDIX D

PROJECT TIMELINE

Month	Activities
May 2013	Complete AANA wellness modules
August 2013	Complete Collaborative Institutional Training Initiative (CITI)
September 2014	Submit graduate committee chair and member names (3) to NAP
April 2015	Submit Institutional Research Board (IRB) application for process approval
July 2015	Application submitted for Degree and Plan of Study
July 2015	Submit Contact Graduate Reader form to the Reviewer of Graduate Nursing Capstone Projects
July 2015	Defense of Proposal and submission of approval form. Submission of title page
August – September 2015	Data Collection
September 2015	Capstone paper corrections. Rework data interpretation
October 2015	Final presentation/Capstone defense.
October 2015	Submit copy of capstone project to Graduate Reader for proofing and approval
December 2015	Graduate

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