A Review of Opioid Use for Pain in Adult Patients with Traumatic Injuries

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Date of Submission: January 10, 2020

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Abstract

Purpose: To evaluate the impact and effectiveness of New Jersey (NJ) Senate Bill 3 in reducing the use of opioids in the treatment of pain for the trauma patient in the inpatient setting. The goal of this project was to examine the prescribing practices of practitioners and the patients use of opioid pain medications in the hospital setting prior to, and after the enactment of Senate Bill 3.

Methodology: This project was a single center retrospective review which took place at an American College of Surgeons verified Level I Trauma Center in NJ. In all, a total of 2,043 patient charts for calendar years 2016 and 2018 were reviewed. Injury Severity Score (ISS) and Morphine Milligram Equivalents (MME) were recorded by patient and the data between the two years was compared to ascertain opioid consumption pre and post the Senate Bill enactment. Patients prescribe opioid drips, methadone, or fentanyl patches were excluded because the data available did not allow for accurate conversion to MME. After applying these exclusion criteria, a total of 1,688 patients charts remained.

Results: The average daily MME consumption dropped from 14.1±0.48 MME/day in 2016 to 8.78±0.33 MME/day in 2018. This represents a 38% decrease with $p<0.001$ in inpatient opioid use over a similar length of stay (LOS, 4.34±0.14 versus 4.41±0.13 days) of patients in both years. The total MME consumed per person decreased form 77.0 MME/stay to 44.8 MME/stay, a nearly 42% decrease in opioid consumption during inpatient treatment. While the injury severity score (ISS) of patients was higher in 2018 than in 2016 (10.6±0.21 vs. 9.09±0.19, $p<0.001$) still less opioid was used in 2018. Also, trauma patients in 2018 were approximately 4.2 years older than in 2016 (59.9±0.69 years in 2018 vs. 55.7 ±0.71 years in 2016, $p<0.001$).

Implications for Practice: This retrospective review demonstrated that one single entity cannot correct a multi-tiered societal problem. Medical professionals, legislators, community leaders,

and the community itself must work in a collaborative fashion to employ meaningful and multifaceted solutions to solve the opioid crisis.

***Keywords*:** opioid, trauma, deaths, laws, prescribing

A Review of Opioid Use for Pain in Adult Patients with Traumatic Injuries

The focus of this project was directed to the traumatically injured patients and the methods used to address and control their pain. This single center retrospective review studied the medications used in pain management practices for the trauma patient prior to, and since the enactment of New Jersey Senate Bill 3 which restricts the outpatient prescribing of opioids. The setting for this project was an American College of Surgeons (ACS) verified Level I Trauma Center in New Jersey which admits more than 1500 trauma patients a year.

Treatment of the trauma patient includes three pillars of care; physical healing, mental/emotional healing, and the management of the patient's pain during the healing process. Following a traumatic injury, a patient may undergo several weeks or months of medical treatment in the hospital. Often this treatment includes surgery, stabilized recovery, followed by physical therapy and rehabilitation. Throughout this process, the management of the patient's pain has a significant impact. Pain management is a significant pillar in the treatment and recovery of these patients (Sarani, 2019).

For many years the standard treatment for pain management of the trauma patient has been through the use of extended release and short acting opioids. Trauma patients are prescribed opioids during their hospital stay to control and manage their pain as they recover. Often, the use of these opioids continues after their hospital stay to further manage their pain. What begins as a pain management tool sometimes becomes an addiction. As the availability of legal and illegal opioids has become more prevalent in our society, abuse of these drugs has reached dangerous levels. With the recent public awareness and outcry focused on drug addiction and death associated with opioid abuse, medical professionals are evaluating current practices and exploring alternatives to the use of opioids in pain management practices.

Background & Significance

It is an unfortunate reality that traumatic injuries occur every day in our society. Often without warning, a person's life is turned upside down due to an event which leaves them critically injured. From work related incidents, accidents at home, or motor vehicle crashes, these traumatic experiences come in all forms and the trauma center is there to treat these people at a moment's notice.

To begin, it is relevant to define the trauma patient. The ACS COT defines the trauma patient based on the National Trauma Data Bank's (NTDB) set of standard inclusion criteria. This general inclusion criterion includes a patient sustaining one or more traumatic injuries within the International Classification of Disease (ICD) 10 codes between S00-S99, T07, T14, T20-T28, T30-T32, T79.A1-T 79.A9 and is admitted to or observed in the hospital for management of those injuries (American College of Surgeons Committee on Trauma, 2019).

Trauma patients are assigned a number based on the severity of their injuries, known as Injury Severity Score (ISS). The ISS is based on the Abbreviated Injury Scale (AIS) which calculates the patient's injury status through a standard algorithm to provide a uniform national basis for determining the severity of patient's injuries. This provides medical institutions the ability to track and monitor trauma patients based on a standard. According to the American College of Surgeons Committee on Trauma, an ISS of greater than 15 is used to define a major trauma patient (2018).

Beyond the technical definition of the trauma patient, it is useful to apply a more humane definition and to describe the common threads that connect most trauma patients. Trauma is a young person's disease and is the leading cause of death among people between the ages of 1-46 years old (National Trauma Institute, 2017). Further, consider that in the United States the age

group with the highest death rate from drug overdose are those 25-54 years old (Kaiser Foundation, 2018). It is clear that the range of population most likely to experience a traumatic event overlaps the age group most susceptible to substance abuse.

The first and primary issue in common amongst most trauma patients is the suddenness and shock of the circumstance. Most people do not wake up in the morning with the knowledge that they will end up in a trauma center before the conclusion of the day. When the mishap occurs; the suddenness, severity, and shock of the circumstance leaves the patient and their loved ones confused and vulnerable.

The next common thread is the uncertainty. The patient and their families search for answers to the potential of recovery, the disabilities that they may face, and the long road to recovery. In addition to these physical concerns is the concern relative to the financial impact to the family; especially if the critically injured patient is the primary breadwinner for the family. Will the family be able to financially survive while the critically injured patient recovers and what will they do as financial pressures mount? While the injuries to the patient are physical, there too are a whole host of emotional issues that exacerbate the situation and can impact the recovery of the patient and their family.

Traumatic injuries come in many forms and with varying degrees of pain. From head injuries to multiple open fractures of extremities, or multiple rib fractures with internal injuries, no two trauma patients are alike. Of these, rib fractures in the trauma population are considered the most painful and pose a significant risk of morbidity and mortality (Sarani. 2019). Further, the pain associated with other injuries varies based on a number of conditions. Some of these conditions include: the pain tolerance of the individual, or the type and severity of the injury. The experience of each trauma patient is different and each patient's pain must be treated based

on their particular circumstance. A dose of medication which is effective for one patient, may not begin to address the pain of the next trauma patient.

Historically, the cornerstone for pain management for the trauma patient for many years has been through the use of opioids. Opioid medication given at regular intervals has been one of the most effective tools available to address pain associated with traumatic injuries and the requisite long recovery period. As is widely known, use of opioid medication over a long period of time can become addictive. For the trauma patient, this is of particular concern because of the long recovery period associated with traumatic injuries. As an example, healing of a fracture often takes between 6-8 weeks to occur in a healthy patient (Legome, 2019). It is often difficult for the practitioner to know when a medication being prescribed for pain management to address the trauma patients' pain, has turned to become a medication being used at the early onset of addiction for a trauma patient. Addiction could present another complication in the recovery process of the trauma patient.

An opioid used for pain management leading to an addiction on the part of the trauma patient has been a long-standing concern amongst practitioners. The measure of pain is subjective. The patient recovering from their injuries describes their level of pain to the practitioner and medications are prescribed to address that pain. For the addicted patient, they may exaggerate the description for the level of pain they are feeling in an effort to obtain more opioids to address a growing addiction. When the practitioner determines that the use of opioids is no longer necessary for the patient's treatment, left undiagnosed the now addicted patient looks to other means to satisfy the urge of addiction. Unfortunately, the medication that was once prescribed to help the patient through the treatment of their traumatic injuries has manifested itself into another medical issue for the patient; addiction.

With the widespread use of opioids for pain management over the last decade or more, the number of patients who have become addicted to opioids has exploded. Unfortunately, opioids initially used to help in the healing process have become a gateway to other more serious drug use. Patients no longer prescribed opioids look for other drugs to satisfy their needs which has contributed to the drug abuse issues the country now faces.

Opioid addiction has become a social and economic crisis in the United States. As medical professionals it is prudent to find ways to eliminate any possibility that any patient at the conclusion of their treatment would leave with an addiction. A single patient addicted is one too many.

The social crisis created by opioid addiction has deep and longstanding effects on our society. Beyond the impact on the individual addicted, addiction impacts the immediate and extended family as well. From dealing with the daily issues associated with the addicted person, the emotional strain experienced by loved ones, and in some cases the breakdown of the family, the effects of addiction are far reaching. Addiction too can lead to crime to support the addiction, in some cases financial ruin of the family, and finally the death of the addicted person.

With the growing concerns surrounding addiction, pain management has begun to evolve in the medical community. In recent years studies have been conducted exploring other pain management strategies which revolve around non-opioid medications. These studies have largely focused on pain management for afflictions unrelated to trauma. Many of these studies have shown promise in the management of pain; it is a natural evolution to apply some of these same treatment methods to trauma patients to determine if non-opioid treatments will be successful for these more severely injured patients.

A roadblock to the application of other treatments for pain has been cost. Opioids are both very effective and a low-cost treatment for pain. Medications used in alternate treatment methods generally cost significantly more than opioids. Cash strapped medical organizations struggle with the business decision to promote the lower cost use of opioids for pain management versus the more expensive non-addictive alternatives. While the initial cost of treatment using opioids is much lower, the total overall cost of this treatment is much higher when the medical organization includes addressing the resulting addiction. As social pressure mounts surrounding the drug addiction explosion, it is difficult for organizations to ignore the need to support alternate non-addictive treatment methods, despite the increase in initial cost (NIH, 2018).

Pain management is a key pillar to the treatment of trauma patients. With opioid use, opioid addiction, and opioid deaths on the rise in our society, the medical community is expediting studies and research poised to find non-opioid methods to manage pain, regardless of the cost of treatment. The treatment of trauma patients with new pain management medications, guidelines, and methods is the next evolution of care.

Needs Assessment

Although the treatment of pain with opioids has proven to be very effective, over prescribing and extending prescription duration has resulted in addiction amongst a segment of the patient population. In 2016, more than 64,000 deaths of Americans have been attributed to opioid abuse (CDC, 2017). In 2017, there were 1,969 opioid overdose deaths in New Jersey (22.0 deaths per 100,000 persons), which was 50% higher than the national rate of 14.6 deaths per 100,000 persons (National Institute on Drug Abuse, 2019). Since the passing of Senate Bill 3, death from opioid overdoses in New Jersey continues to rise even as medical prescriptions for

opioids continue to steadily decrease (The State of New Jersey Department of Law & Public Safety Office of the Attorney General, 2018).

With the passage of the Affordable Care Act in 2010, the Centers for Medicare and Medicaid Services (CMS) rules regarding patient satisfaction became a measurement tied to the reimbursement of institutions for providing patient care. Of these patient satisfaction requirements, pain management was part of the requirements. Healthcare institution lobbying bodies have successfully argued that the inclusion of pain management in the patient satisfaction requirements established by CMS for reimbursement, has forced practitioners to overprescribe opioids for pain management in an effort to receive acceptable patient satisfaction scores and thus the requisite reimbursement for their services. In 2016, without admission of the link between patient satisfaction requirements and reimbursement, CMS changed their requirements to no longer include pain management as a criterion required for reimbursement (CMS, 2016). Some have lobbied that what was intended to be an effort to improve healthcare through patient satisfaction measures, has actually led to the explosion of opioid addiction, overdose, and deaths.

With opioid addiction, overdoses, and deaths reaching epic proportions in the United States, the government has continued to act. In 2017, the United States government enacted a bill to empower the medical community and law enforcement to further combat the opioid epidemic. This legislation includes grants to expand education, prevention, treatment, reporting, and referrals to deal with opioid related problems (Stem the Tide of Overdose Prevalence from Opiate Drugs Act, 2017).

The State of New Jersey too has responded to the opioid epidemic. In May 2013, the State Legislature passed the Overdose Prevention Act. This legislation is aimed at encouraging people to seek medical assistance whenever a drug overdose occurs. This legislation further

restricts the legal ramifications of both the individual experiencing the overdose and the person placing the call for help. This legislation was further enhanced in 2015, through the addition of naloxone administration regulations. New Jersey now permits certified Emergency Medical Technicians-Basics (EMT-B) the ability to carry and administer naloxone (NJ DOH OEM, 2015). Should an opioid overdose be suspected, EMT-B's can administer naloxone at the scene as a means to begin to immediately treat the suspected overdose. This legislation is intended to grow educational efforts related to opioid abuse and save lives through the treatment of overdoses. While it is widely believed that the enactment of this legislation and the resulting immediate treatment has saved lives, the empirical data regarding the results of this effort have not yet been published.

The Overdose Prevention Act was further expanded in February 2017. The 2017 amendment permits over the counter purchase of naloxone without a prescription. Pharmacies in the State of New Jersey are now permitted to sell naloxone over the counter to anyone who believes they have a need to have the medication. This amendment is intended to encourage family members and friends of suspected drug addicts to have naloxone on hand to immediately treat a suspected overdose. Again, the intent of this amendment is to prevent deaths due to overdose.

In a separate act, New Jersey passed Senate Bill 3 in March 2017 which evoked stricter prescribing restrictions which forced healthcare systems and healthcare providers to change their current practices. This legislation restricts the amount of opioid medications a practitioner can prescribe at a single medical visit for a patient presenting a given medical condition. These limits prevent prescription doses from exceeding 5 days in duration without requiring another appointment with their healthcare provider. In addition, long-acting opioid medications are no

longer permitted to be prescribed without specific and restrictive monitoring in place, or in special circumstances (S. 3, 2017). In addition, this legislation established the New Jersey Prescription Monitoring Program (NJ PMP). This is a statewide data base of patients and historically tracks the prescription medications that they have been prescribed.

At both the Federal and State level, various efforts continue in an attempt to stem the spread of the opioid epidemic. We expect that for the next several years, legislation aimed at education, prevention, and treatment of opioid addiction will continue. As medical professionals, our effort must focus on providing alternative treatments for pain and pain management so that those patients prone to addiction can be safely treated with non-addictive medications.

Problem Statement

This project was a retrospective review aimed at evaluating the opioid pain management practices for trauma patients since the enactment of NJ Senate Bill 3. This project shall compare the clinical prescribing methods of opioids used to control pain prior to the legislation, against the pain management methods used since the enactment of the legislation. This legislation restricted the use of long-acting opioid medications and the prescription duration.

Clinical Question

For adult patients 18-89 years of age admitted to the hospital trauma service, has the legislation limiting the outpatient use of opioid prescriptions for acute pain changed the prescribers' practice and patient consumption of opioids in the inpatient hospital setting?

Aims and Objectives

The aim of this project was to evaluate the impact of recently passed legislation regarding the restriction of opioid prescriptions and its effectiveness in reducing the use of opioids in the treatment of pain for the trauma patient in the inpatient setting.

Objectives for this project include:

- Quantify the use and frequency of opioid administration for trauma patients prior to the enactment of the legislation (2016).
- Quantify the use and frequency of opioid administration for trauma patients since enactment of the legislation (2018).
- Normalize the data gathered for both data sets to Morphine Milligram Equivalents (MME) as a common base of comparison of the data.
- Summarize the results.

Review of Literature

Literature review (see Appendix A for evidence table) of this issue begins with the political response to the alarming increase in opioid deaths over a relatively short span of time. As the spotlight was placed on the increase in opioid related deaths, politicians anxious to regulate the healthcare industry sought to enact legislation to satisfy constituent outcry relative to the issue. As a result, state legislatures passed a wide variety of laws aimed at limiting the prescription of opioids. These laws vary widely from state to state often with little consistency. Davis, Lieberman, Hernandez-Delgado, & Suba conducted a systematic multi-source legal review of mandatory state laws looking at the consistency of opioid legislation (2019). Variations in prescribing duration, guidelines surrounding prescription exemptions, and the medications covered in the laws are some of the key discrepancies found. As 26 states passed opioid prescribing laws, 65% (17/26) were passed in 2017, there was little overall consistency in their content (Davis, Lieberman, Hernandez-Delgado, & Suba 2019). According to Davis, Lieberman, Hernandez-Delgado, & Suba "to date, there is no data on whether and to what extent these laws mediate opioid-related morbidity and mortality" (2019).

A feature of many of these laws was measures to monitor prescriptions on a global scale. Again, these efforts vary from state to state and have resulted in a variety of systems to monitor individual drug prescriptions for the patient. Widely known as Prescription Drug Monitoring Programs (PDMP), these databases have been implemented across many states (Davis, 2019 & Whitmore, 2019). In several states, legislators implemented laws without including input from key stakeholders (Whitmore et al, 2019).

Some studies are beginning to reveal that controlling the prescription rate and quantities through laws and legislation may not be having a significant impacting in stemming the tide of opioid abuse and related deaths. Romeiser, Labriola, & Meliker conducting a Poisson Regression analysis of data gathered between 2013-2015 in New York State found that a reduction in opioid prescriptions did not equate to a reduction in opioid related deaths (2019). The growing use of illegal fentanyl is negatively impacting prescription limitation efforts placed on legal opioid medications (Romeiser, Labriola, & Meliker, 2019).

The results of Romeiser's 2019 analysis was consistent with the question raised by Davis. Davis questioned whether the increase in restrictions in opioid prescriptions was actually having a meaningful impact on the increase in opioid related deaths. Romeiser's analysis, although limited to New Your State, revealed that the legislation had no impact on reducing opioid related deaths. His work revealed that there are demographic "hot spots" indicating that factors such as socioeconomics, education, and other stressors have a part in the opioid crisis as well.

Specific to the hospital environment, a cross sectional survey of physicians, advanced practice providers, and pharmacists was performed in 2018. This electronic cross-sectional survey revealed that 61.7% of the respondents felt that opioids were overused in an effort to achieve better patient satisfaction (Oyler et al, 2018).

The [redacted] trauma service in 2014 implemented a pain management program that emphasized the use of non-opioid medications for pain and focused on patient education when opioids were used as a pain treatment measure. As a result of the retrospective study conducted in 2018, there was a statistical significance ($p<0.001$) of lowered opioid use in patients discharged from the trauma service having received a greater level of education relative to the use of opioid medication for their control of pain (Oyler et al, 2018). Romeiser came to a similar conclusion in that not only greater patient education was important, but that further analysis of the demographic areas hardest hit by the opioid crisis and interventions to address the local factors contributing to the addiction in that region needed to be identified and addressed (2019).

A large national cohort retrospective study conducted between 2006 and 2012 comprised of over 33,000 patients across several medical centers and states was summarized with a revealing conclusion. "The incidence of opioid prescription at discharge (54.3%) closely matches the incidence of moderate to severe pain in trauma patients, indicating appropriate prescribing practices. We advocate that injury severity and level of pain – not arbitrary regulations – should inform the decision to prescribe opioids" (Chaudhary et al, 2017).

> "Results among the 33,762 patients included in the study (26,997 [80.0%] men; mean [SD] age, 32.9 [13.3] years), 18,338 (54.3%) received an opioid prescription at discharge. In risk-adjusted models, older age (45-64 vs 18-24 years: odds ratio [OR], 1.28; 95% CI, 1.13-1.44), marriage (OR, 1.26; 95% CI, 1.20-1.34), and higher Injury Severity Score (≥9 vs <9: OR, 1.40; 95% CI, 1.32-1.48) were associated with a higher likelihood of opioid prescription at discharge. Male sex (OR, 0.76; 95% CI, 0.69-0.83) and anxiety (OR,

0.82; 95% CI, 0.73-0.93) were associated with a decreased likelihood of opioid prescription at discharge" (Chaudhary et al, 2017).

A narrative review conducted by Karamchandani, Klick, Dougherty, Bonavia, Allen, & Carr discussed the use of pain management practices in an intensive care unit setting and concluded that prospective clinical trials were needed to analyze the implementation of alternative pain management medications and techniques to address acute pain (2019). This observation concurs with Oyler's work at the [redacted] where a non-opioid pain management program was implemented to address pain management and education for the trauma patient prior to discharge (2019).

As alternative treatment for the use of opioids in pain management, alternative pain management protocols will need to be studied and implemented. Research in this area revealed some work already done which shows moderate to promising results in the non-opioid treatment of pain. While these studies are not conclusive, they do reveal that more research needs to be done.

A pain management study by Esmailian explored the use of intravenous acetaminophen with morphine for patients with rib fractures was a double-blind randomized control trial (Esmailian, 2015). This study was conducted in Iran and had little participation, lacked the use of placebos, and did not provide latitude to change the prescribed treatment method during the course of the trial. The study concluded that there was little difference in the outcome relative to patients' pain, regardless of the medication used (Esmailian, 2015). The study allowed a 30-minute interval after the administration of intravenous acetaminophen to relieve pain before a rescue dose of morphine was given. This study concluded that there was very little difference between the results of using intravenous acetaminophen or morphine alone. Thirty minutes after

drug administration the mean of pain severity were 5.5 ± 2.3 and 4.9 ± 1.7 in morphine and acetaminophen groups, respectively (p=0.23) (Esmailian, 2015). Success rate in morphine and acetaminophen groups were 58.6% (95% Cl: 39.6-77.7) and 80% (95% Cl: 63.2-96.7), respectively, (p=0.09) (Esmailian, 2015).

There were several studies found which discussed pain control methods comparing intravenous acetaminophen with multimodal pain medications. These studies were conducted in patients having surgical procedures. Of these studies; two were literature reviews, one was retrospective, and the last was a randomized double-blind clinical control trial. Sun, Zhu, Zou, Li, & Han (2018) conducted a literature review and O'Neal et al. (2017) a double blind randomized control trial. Both concluded that intravenous acetaminophen when added to multimodal analgesia had little significance in improving pain relief for the patient. A literature review conducted by Yang, Du, & Sun evaluated four studies involving 865 participants. The meta-analysis showed that there were significant differences between groups in terms of pain scores at Post-Operative Day (POD) 1 (WMD = -0.954, 95% CI: -1.204 to -0.703, P = 0.000), POD 2 (WMD = -1.072, 95% CI: -2.072 to -0.073, P = 0.000), and POD 3 (WMD = -0.883, 95% CI: -1.142 to -0.624, P = 0.000). Significant differences were found regarding opioid consumption at POD 1 (WMD = -3.144, 95% CI: -4.142 to -2.146, P = 0.000), POD 2 (WMD = -5.665, 95% CI: -7.383 to -3.947, P = 0.000), and POD 3 (WMD = -3.563, 95% CI: -6.136 to -0.991, P = 0.007) (Yang, Du, & Sun, 2017). The retrospective study conducted by Hansen et al. (2018) found that the use of intravenous acetaminophen decreased the opioid use in the treatment of pain.

Among 61,017 cholecystectomy patients, 31,133 (51%) received IV APAP. Subjects averaged 51 and 57 years of age, respectively, in the IV and oral APAP cohorts. In the

> adjusted models, IV APAP was associated with 0.42 days shorter LOS (95% CI = -0.58 to -0.27; p < .0001), $1,045 lower hospitalization costs (95% CI = -$1,521 to -$569; p < .0001), 2 mg lower average daily MED (95% CI = -3 mg to -0.9 mg; p = .0005), and lower rates of respiratory depression (odds ratio [OR] = 0.89, 95% CI = 0.82-0.97; p = .006), and nausea and vomiting (OR = 0.86, 95% CI = 0.86-0.86; p < .0001)
>
> Hansen et al. 2018

The next subject investigated was the management of treatment and associated treatment protocols, specifically to control pain for the trauma patient. There were several studies discussing these topics. All of the studies reviewed agreed on one important concept; early intervention and immediate initiation of a pain management protocol was critical in the treatment of these patients (Carrie, 2017; Fabricant, 2013; Oyler, 2015; Sahr, 2013; Unsworth et.al, 2015; Witt & Bulger 2017).

Each study had differences in their approach and treatment methods. Some chose a surgical intervention, others a multimodal analgesia approach. Most of these studies followed a multi-tiered protocol to the patient's treatment and consistently followed the established guidelines. These protocols and guidelines included a multi-disciplinary approach to treatment which included mobilization of the patient, surgery, respiratory care, and pain management. In addition, discussions of preventing other medical complications brought on by the injuries were addressed in the protocols (Carrie, 2017; Fabricant, 2013; Oyler, 2015; Sahr, 2013; Unsworth et.al, 2015; Witt & Bulger 2017).

Several of the studies discuss avoidance of opioids or administering opioids as last resort within their protocol and guidelines. These studies recognized the addictive effects of opioids and carefully monitored their administration. Most detailed a multimodal analgesia approach to

treatment as the first step with the addition of opioids only after monitoring patient's response to analgesia treatment (Carrie, 2018; Fabricant, 2013; Oyler, 2015; Sahr, 2013; Unsworth et.al, 2015; Witt & Bulger 2017). The studies also recognized the limitations of using non-opioid analgesia and suggested combinations of these medications as the initial approach to pain management.

Another area reviewed was the impact on quality of life relative to the treatment protocols and guidelines. Quality of life included both in hospital and post hospital treatment. Several studies discussed the importance of shortening the treatment cycle thereby decreasing the hospital length of stay and the associated benefits to the quality of life for the patient (Curtis, 2016; Dhillon, 2014; Fabricant, 2013; Flarity, 2017; & Marasco, 2015). To achieve this, the studies discussed early intervention with medications to begin offering immediate relief for pain. These studies too focused on the importance of multidisciplinary care of the patient as part of standard treatment protocol including mobilization, respiratory therapy, and pain management. Discussion regarding pain management in each of these studies encompassed a multimodal analgesia approach (Bugaev, 2016; Curtis, 2016; Dhillon, 2014; Fabricant, 2013; Flarity, 2017; & Marasco, 2015). These studies discussed the importance of recognizing and avoiding secondary medical complications in the treatment of the patient. The studies argue that the increase in length of hospital stay (LOS) leads to a prolonged recovery period, post hospital. The studies go on to state that with a decreased hospital stay, decreases the possibility of pulmonary complications. They go on to conclude that the short hospital stay and the shorter treatment period lead to less opioid use by the patient (Curtis, 2016; Dhillon, 2014; Fabricant, 2013; Flarity, 2017; & Marasco, 2015).

Theoretical Framework

The Academic Center for Evidence-Based Practice (ACE) Star Model of Knowledge Transformation was used to retrospectively review the clinical practice involving opioid prescribing (Stevens, 2012). This retrospective review evaluated the impact of administering opioids for the treatment of acute pain in adult trauma patients admitted to the trauma service and assessed if the use of opioid medications has decreased or increased since the enactment of the NJ opioid prescribing law for acute pain.

The ACE Star Model was ideal for this retrospective review in evaluating the various stages of change in opioid prescribing methods, as newly discovered information is moved into practice. The ACE Star Model outlines the necessary steps needed to evaluate this project (see Appendix B for ACE Star Model of Knowledge Transformation). The ACE Star Model of Knowledge Transformation is a five-step process; knowledge discovery, evidence summary, translation to practice recommendations, practice integration, and process, outcome evaluation (Stevens, 2012).

Methodology

This study was a single center retrospective review which took place at an American College of Surgeons verified Level I Trauma Center in NJ. This project reviewed the opioid prescribing practices of practitioner's, and patient consumption of opioids in the inpatient hospital setting for pain management comparing pre-Senate Bill 3 practices with post-Senate Bill 3 practices. This study reviewed all adult patients admitted to the trauma service in 2016 and in 2018. Data regarding dosages were converted to MME to provide a consistent unit of comparison.

NJ Senate Bill 3 was enacted in March of 2017. The statistics for this project were limited to trauma data collected from two individual calendar years; 2016 and 2018. The data collected in 2016 captures patient information in the calendar year prior to the passage of Senate Bill 3, and data collected in 2018 was the first full calendar year after the passage of this bill. The raw data collected for these two years contained all records from trauma patients who were treated in this NJ Level I Trauma Center in those respective years. In all, a total of 2,043 patient charts were reviewed; 1,033 for 2016 and 1,010 for 2018. ISS and MME were recorded by patient and the data between the two years was compared to ascertain opioid consumption. Patients prescribed opioid drips, methadone, or fentanyl patches were excluded because the data available did not allow for accurate conversion to Morphine Milligram Equivalents. After applying these exclusion criteria, a total of 1,688 patients charts remained; 854 for 2016, and 834 for 2018. The data was then analyzed for statistical significance using the chi-square and t-test. The statistical software program utilized for this analysis was Minitab 17. Statistical significance was established as $p<0.05$ for all data analysis.

Design of Project

The design of this project had numerous steps of discussion, planning, and approval. The benefit of this project was timing. Currently, opioid abuse is a leading societal issue. Medical organizations are urgently seeking to understand the use of opioids and explore alternatives in pain management. When the concept of this project was presented, it received immediate interest and support. The following describe the steps followed for the design of this project:

1. *Secure Doctor of Nursing (DNP) Chairperson* - Dr. Kamienski accepted the project proposal and is the chair for this project.

2. *Secure Faculty Doctoral Team Member* - Dr. Forrester accepted and provided faculty support for the project.
3. *Present the project concept to the Trauma Medical Director (TMD)* - This project concept was presented to the Trauma Medical Director and received his immediate approval and support.
4. *Present the concept to the Chief Medical Officer (CMO)* - With the Trauma Medical Director's approval, the project was then presented to the Chief Medical Officer and approval was received to proceed with this study.
5. *Present the project concept to the Chief Nursing Officer (CNO)* - Again, with the project approved by the TMD and the CMO, the CNO approved and strongly supported the project.
6. *Obtain letter of cooperation* – "Letter of Cooperation" was obtained from the trauma center granting approval to conduct research at their facility (see Appendix C for letter of cooperation).
7. *Request Nursing Research Council approval* - The project received approval from the Nurse Researcher and the Nursing Research Council. (see Appendix D for Nursing Research Council approval).
8. *Request Institutional Review Board (IRB) approval* - Requested IRB approval from the trauma center's IRB to utilize the existing trauma database. IRB approval was granted (see Appendix E and Appendix F for IRB approval).
9. *DNP Chair project review meeting* - Project review meeting with DNP chair to review Rutgers IRB document prior to submission.

10. *IRB approval from Rutgers University* - IRB approval received from Rutgers (see Appendix F for Rutgers IRB approval).
11. *Data collection* - The existing trauma registry was used to collect general demographic information for each case in the study. The existing patient charts were used to collect information regarding the prescribed pain management approach.
12. *Data analysis* - Retrospectively reviewed the trauma registry and patient records for 2016 and 2018 and compared the administration of opioids for pain management.
13. *Compile and document results* - Based on the retrospective review, the data was compiled and correlated to determine if Senate Bill 3 made a difference in the prescribing practices of practitioners, and if it was effective in reducing the amount of opioid used for pain management.
14. *Disseminate results* - Prepare and publish a research article documenting the findings of the study. The goal is to have this article published in a peer reviewed journal.

Setting

This retrospective review was conducted at a single site. This medical center is a 687-bed acute care facility located in New Jersey. It is an American College of Surgeons verified Level I Trauma Center, and a designated Level II Trauma Center in the State of New Jersey which admits over 1500 trauma patients a year. The trauma emergency department consists of three trauma rooms with a total capacity for six trauma patients. In addition, the trauma service oversees the care of the admitted patients in the surgical intensive care unit and on surgical floors 24 hours a day 7 days a week.

Study Population

The study population was limited to those patients admitted to the trauma service. The inclusion criteria for the study were those patients admitted with a traumatic injury and were adult patients 18-89 years of age. The study set to compare 2016 patient records with the 2018 patient records. Those patients excluded from the study group are those patients that are pediatric patients 0-17 years of age, adult patients greater than 89 years of age, and pregnant patients. Patients prescribed opioid drips, methadone, or fentanyl patches were also excluded.

Study Interventions

This was a retrospective review of opioid administration to patients; no study interventions were employed.

Outcome Measures

Patient health information was analyzed to determine the results of this study. Specifically, the existing trauma database and patient charts were reviewed. This data analysis was performed in a secure environment at the medical center. Data collection did not include patient's personal information or identifiers; therefore, patient's personal information was not compromised, and a patient waiver was not required. A list of data collection points was prepared and used for the analysis of outcomes (see Appendix G for collection data points).

Benefits/Risks

The benefit of this study was to review the impact of legislation passed in 2017 in the State of New Jersey limiting the opioid prescription practices of practitioners. The intent of this review was to determine if changes to prescribing laws had a beneficial impact in the reduction of opioid use for the treatment of pain in trauma patients. As no measures were implemented as part of this review, there are no identified risk factors to consider.

Subject Recruitment

For this project, the subjects involved were patients admitted to the trauma service at the medical center. Data was obtained from the medical center's Digital Innovations Version 5 Trauma Registry.

Historical trauma data from this medical center revealed that in a typical year the trauma service adult patient mix (18-89 years of age) consists of: 81% of patients identified as white, 5% as African American, 1% as Asian, and 13% as other. Additionally, of these patients 43% were woman and 55% males. The historical data relative to age revealed that 16% were between the ages of 18-32, 15% were 33-47 years of age, 21% were 48-62 years of age, 23% were 63-77 years of age, and 25% were 78-89 years of age.

As this retrospective study involved patients admitted to the trauma service, recruitment of specific participants was not required. The blend of patients roughly mirrored the breakdown cited above. All patients during the subject period were included in the study and for this reason, the demographic cross section of patients including race, gender, and age, are unpredictable. The diverse cross section of patients provided a meaningful study result.

Consent Procedures

This project was a retrospective review of treatment results over two specific annual periods. Patient personal information was not included as part of this study and therefore patient consent was not required or obtained.

Subject Cost and Compensation

For this project, there was no additional cost to the hospital for conducting this retrospective review.

Project Timeline

The timeline for this project was approximately two years (see Appendix I for the Gantt chart). The critical milestones for the project included obtaining Institutional Review Board (IRB) approval from the study site on March 27th, 2019, and IRB approval from Rutgers on June 18, 2019. Completion of data collection from the study site database on November 22, 2019, and compiled the data to ascertain results December 27, 2019. Presentation of final Doctor of Nursing Practice proposal for Rutgers on January 10th, 2020.

Evaluation Plan

A retrospective review was used to analyze the impact of Senate Bill 3 relative to opioid prescribing practices in the inpatient setting. Collection and recording of the patient information followed standard hospital protocol and this data was maintained in the existing hospital record keeping systems. Evaluation of the data followed a strict methodology intended to eliminate subjectivity or the risk of bias interpretation. The data collection data points in the data collection tool were objectively followed.

Data Maintenance/Security

All information relative to this study was maintained in the secure patient record servers at the medical center. This information was kept behind a secure electronic data firewall maintained by the hospital information technology staff. All of the medical center computers/servers are password protected. Data has been de-identified and will be stored for 2 years after the research article is published.

Results

Senate Bill 3 was intended to affect prescribing practices for the outpatient administration of opioid medications. The purpose of this project was to determine if this Senate Bill also had

an impact on inpatient prescribing practices and patient consumption of opioids in the hospital setting. From review of the statistical analysis of the data, prescribing practices and inpatient consumption was reduced after the enactment of Senate Bill 3.

This project was a single center retrospective review. The statistics for this project were limited to trauma data collected from two individual calendar years; 2016 and 2018. The data collected in 2016 captures patient information in the calendar year prior to the passage of Senate Bill 3, and data collected in 2018 was the first full calendar year after the passage of this bill. Senate Bill 3 was enacted in March of 2017. The goal of this project was to examine the prescribing practices of practitioners and the patients use of opioid pain medications in the hospital setting prior to, and after the enactment of this Senate Bill.

The raw data collected for these two years contained all records from trauma patients who were treated in the ACS Level 1 Trauma Center in those respective years. In all, a total of 2,043 patient charts were reviewed; 1,033 for 2016 and 1,010 for 2018. Comparing the number of patient records, the project reflects a similar patient count between the two years providing an even distribution of patient records for this project.

The raw data was further refined to restrict the project to a broadly defined patient segment. Patients not admitted to the trauma service, pregnant women, and pediatric patients were removed from the data set. In addition, patients prescribed opioid drips, methadone, or fentanyl patches were also removed from the data set as the data available did not allow for an accurate conversion of the dosing for these patients at any given time. Finally, the project was limited to patients over the age of 18 years and under the age of 90. After applying these exclusion criteria, a total of 1,688 patients charts remained; 854 for 2016, and 834 for 2018.

The data extracted from patient records was limited in scope focusing on a few key elements. The patient's age, gender, ISS, length of stay in the hospital, average MME administered per day, and total MME per hospital stay were recorded. The remaining patient information from the patient charts was disregarded.

Not all patients were prescribed the same pain medication. For example, one patient may have received hydromorphone while another patient may have received intravenous fentanyl or a combination of opioid medications. As medication strength varies from one medication to the next, these medications were converted to a common measurement providing a consistent comparison of dosing from patient to patient. For this reason, all pain medication dosing were converted to a common measurement, MME. An adult narcotic conversion excel spreadsheet was designed and adapted from the trauma center's pharmacy department to convert all opioids to MME (see Appendix I for adult narcotic conversion reference and Appendix J for adult narcotic conversion spreadsheet).

The data was then analyzed for statistical significance using the chi-square and t-test. The statistical software program utilized for this analysis was Minitab 17. Statistical significance was established as $p<0.05$ for all data analysis. This project received IRB approval from both the medical center and Rutgers University.

Table 1

ISS, MME, & LOS for Opioid Use between 2016 and 2018

	Years		P Value
	2016 (n=854)	2018 (n=834)	
Age ± SEM	55.7 ± 0.70	59.9 ± 0.69	<0.001†
Gender			0.038^
Male	544	514	
Female	310	320	
ISS ± SEM	9.09 ± 0.19	10.6 ± 0.21	<0.001†

Average MME/day ± SEM	14.1 ± 0.48	8.78 ± 0.33	<0.001†
Total MME/stay ± SEM	77.0 ± 3.7	44.8 ± 2.5	<0.001†
LOS ± SEM	4.34 ± 0.14	4.41 ± 0.13	0.718†

Note. ISS = Injury Severity Score; LOS = length of stay. MME = Morphine Milligram Equivalents. † p-value calculated using 2 sample student's t-test. ^p-value calculated using Chi-Square. SEM = standard error of measurement.

The results of the analysis of the data found that the average age of the trauma patient in 2016 was 55.7 with a standard error of measurement (SEM) of ± 0.70. For 2018 the average age of the trauma patient was 59.9 with an SEM ± 0.69. Although this represents a statistically significant difference with a $p<0.001$, it revealed that the trauma patients between the two years were approximately the same age group. In fact, those patients whose average age in 2016 was 55.7, would be 57.7 years of age in 2018.

In 2016 there were 854 patients included in the project data; 544 (64%) male patients and 310 (36%) female patients. In 2018 where there was a total of 834 patients, 514 (62%) male and 320 (38%) female. This did not represent a statistically significant ($p=0.038$) change, it did however represent a reasonably balanced patient sample between the two years.

Based on these three measures; age, number of patients, and gender, the data revealed a balanced project sample of participants which provided for a uniform basis of comparison between the two project years. With these previous elements being similar; comparisons between ISS, LOS, Average MME/day, and total MME/stay between the sample years became more credible.

The average ISS between the two project years were 9.09 and 10.6 respectively, which is statically significant with a $p<0.001$. However, this same data shows that this difference is not clinically significant for the comparison being made between these two groups of patients as the severity of injury is nearly the same.

With the average ISS in 2018 at 10.6 being slightly higher than that of 2016, the average MME consumed per day by the patients decreased significantly in 2018. Average MME consumption per day dropped from 14.1 MME/day in 2016, to 8.78 MME/day in 2018; this represents a 38% decrease in inpatient opioid use over the same average LOS. Further, the total MME consumed decreased from 77.0 MME/stay to 44.8 MME/stay, a nearly 42% decrease in opioid consumption during the patient's inpatient treatment.

The project data was further analyzed through breaking the analysis down into three ISS ranges: ISS less than 9 (see Table 2), an ISS between 9 and 15 (see Table 3), and an ISS greater than 15 (see Table 4). The objective of this continued analysis was to determine if the reduction in opioid consumption was confined to one specific ISS range, or if the reduction was occurring in all ISS ranges. From tables 2, 3 & 4, the data shows a consistent decrease of opioid consumption across the three ISS ranges of 40%-49%. This confirmed that there was a uniform decrease of overall opioid consumption in the inpatient setting regardless of the ISS of the patient.

Table 2

ISS < 9, MME, & LOS for Opioid Use between 2016 and 2018

	Years		P Value
	2016 (n=361)	2018 (n=418)	
Age ± SEM	53.2 ± 1.0	57.0 ±1.3	0.021†
Gender			0.110^
Male	246	262	
Female	115	156	
Average MME/day ± SEM	14.2 ± 0.70	8.58 ± .60	<0.001†
Total MME/stay ± SEM	67.3 ± 4.8	34.6 ± 3.7	<0.001†
LOS ± SEM	3.54 ± 0.20	3.27 ± 0.18	0.305†

Note. LOS = length of stay. MME = Morphine Milligram Equivalents. † p-value calculated using 2 sample student's t-test. ^p-value calculated using Chi-Square. SEM = standard error of measurement.

Table 3

ISS 9-15, MME, & LOS for Opioid Use between 2016 and 2018

	Years		P Value
	2016 (n=389)	2018 (n=264)	
Age ± SEM	58.1 ± 1.1	60.7 ± 0.96	0.068†
Gender			0.447^
Male	237	153	
Female	152	111	
Average MME/day ± SEM	13.6 ± 0.73	8.97 ± .46	<0.001†
Total MME/stay ± SEM	76.0 ± 5.4	45.9 ± 3.4	<0.001†
LOS ± SEM	4.56 ± 0.21	3.85 ± 0.19	0.731†

Note. LOS = length of stay. MME = Morphine Milligram Equivalents. † p-value calculated using 2 sample student's t-test. ^p-value calculated using Chi-Square. SEM = standard error of measurement.

Table 4

ISS > 15, MME, & LOS for Opioid Use between 2016 and 2018

	Years		P Value
	2016 (n=389)	2018 (n=264)	
Age ± SEM	56.8 ± 2.1	62.8 ± 1.5	0.019†
Gender			0.293^
Male	61	99	
Female	43	53	
Average MME/day ± SEM	15.1 ± 1.5	8.6 ± 0.82	<0.001†
Total MME/stay ± SEM	116 ± 14	59.4 ± 7.6	<0.001†
LOS ± SEM	6.55 ± 0.43	6.24 ± 0.37	0.588†

Note. LOS = length of stay. MME = Morphine Milligram Equivalents. † p-value calculated using 2 sample student's t-test. ^p-value calculated using Chi-Square. SEM = standard error of measurement.

The results of this project show conclusively that between 2016 and 2018 there was a statistically significant reduction in inpatient opioid consumption. While the passage of Senate Bill 3 cannot be credited completely for this reduction, it is clear that the heightened awareness

of the opioid crisis played an important role in prescribing practices and consumption related to opioid medications.

Limitations of the Data

This project captured a large majority of the trauma patients treated in the ACS Level I Trauma Center during the years of 2016 and 2018. However, there were some limitations to the study which excluded a total of 355 patients across the subject years. The patients excluded from the project were patients who received opioids through intravenous drips, fentanyl patches, or who were prescribed methadone.

There were two other limitations of the project that should be noted, both were as a result of charting limitations. The first of these limitations was determining what opioid or alternative medications were prescribed verses what was actually consumed by the patient. This data was not collected. The second limitation was documentation of the patient's pain scores throughout their inpatient stay. The charting documentation related to the patient's pain score was inconsistently charted across the group of patient's charts reviewed. While it is assumed that the patient received enough medication to control their pain, without a definitive record of pain scale reporting, it cannot be assured that all patients' pain was controlled.

Discussion and Recommendations

As previously discussed during the literature review of this topic, a spotlight was placed on the increase in opioid related deaths by politicians anxious to regulate the healthcare industry as a whole. They sought to enact legislation to satisfy constituent outcry relative to the growing opioid epidemic spreading throughout the country. As a result, state legislatures passed a wide variety of laws aimed at limiting the prescription of opioids. Studies are now showing that the

passage of these laws and regulations are having limited or mixed results in combating the opioid crisis (CDC, 2019; Romeiser et. al, 2019).

As discovered in the New York State study published in 2019, enactment of state laws limiting opioid prescribing practices had no effect on reducing opioid related deaths (Romeiser, Labriola, & Meliker, 2019). Nationally in 2016 the reported death rate from opioid overdose was 63,938 people (CDC, 2019). The same report for 2018 showed a 6% increase nationally in opioid related deaths to 68,110 Americans (CDC, 2019). New Jersey reported 1,971 opioid related deaths in 2016 (CDC, 2019). This same report for 2018 revealed 2,906 opioid related deaths, a 47% increase (CDC, 2019).

The objective of this study was to determine if the enactment of Senate Bill 3 impacted prescribing practices and consumption of opioid medications in the hospital setting. The research conducted as part of this study showed a statically significant reduction in opioid consumption in the trauma center environment in 2018. The results of this study clearly show a reduction in opioid usage in the controlled hospital setting as a total, and across all individual ISS ranges. If we consider only the objectives of this project, these objectives were achieved. However, if you consider the impact of reduced opioid prescriptions in the hospital setting as it relates to reducing the number of opioid deaths, this effort had no immediate impact.

Although the results of this study showed a significant decrease in opioid consumption in the hospital setting, these results did not directly correlate to a reduction in opioid related deaths in the State of New Jersey. Opioid related deaths in New Jersey continued to increase in 2018 leaving one to conclude that the non-prescribed or illegal use of opioids is still driving the opioid epidemic. Based on the Centers for Disease Control (CDC) data, statistically the reduction of opioid prescribing practices in the State of New Jersey has had no effect on curbing the opioid

related deaths. In contrast to this observation, this study only captures the effects of this legislation one year after its enactment. It would be instructive to monitor the opioid related deaths in subsequent years to determine if the legislation has a more long-term impact. As subsequent years of opioid deaths are observed, it will be difficult to determine if the legislation had its intended effect or if public awareness and education played a stronger role in curbing the use of opioids.

Senate Bill 3 was enacted to limit the number of prescribed opioids in an effort to curb deaths related to opioid consumption. While this bill restricted the availability of these medications, it did not address the overall needs of individuals with acute pain or those already addicted to opioid medications. It stands to reason that those patients with these conditions, not able to get opioid medications through their practitioners, are going to obtain them through other means namely illegal suppliers or illegal opioids (CDC, 2019; Romeiser et. al, 2019). This is an unintended consequent to the Senate Bill and could explain why deaths in New Jersey have increased after its passage.

Implications on Clinical Practice

This retrospective study revealed that Senate Bill 3 did positively impact the prescribing and consumption practices of opioid medications for the inpatient trauma patients. Based on the results of this study, other institutions and practitioners could find this information useful in developing their own clinical practice guidelines. It is also clear however that although the prescription and consumption of opioids was significantly reduced, the entire elimination of opioids for the treatment of pain did not occur. This suggests that there is still a need for opioids in the treatment of pain until other non-addictive alternatives are found.

As with the prescription of all medications, clinical judgement should be used when prescribing opioid pain medications (Chaudhary et al, 2017). The heightened awareness of the dangers of potential addition to opioid medications has clearly impacted the prescribing practices of practitioners. The reduction in opioid consumption in the hospital setting was a result of both the practitioners limited prescribing and monitoring of the patient, and the patients choosing alternative treatments based on their awareness of the dangers of opioid addiction.

Opioid medications are however inexpensive which has led in part to their widescale use for the treatment of pain in the clinical setting. In general, alternative medications are more expensive or less effective than opioids. Until low cost non-addictive alternatives are developed, institutions may be forced to continue more widespread use of opioid medications based on cost.

Implications on Healthcare Policy

Senate Bill 3 addressed one small portion of the overall issue related to opioid use and death, it did not address the entire problem. Opioids were created to provide an inexpensive medication to address pain. This study evaluated the impact of reducing opioid use for pain management in a trauma setting, but several other causes of pain exist across a wide cross-section of the patient population. Restricting the availability of medications without providing low cost non-addictive alternative treatments leaves a whole class of patients searching for relief. Without clinically driven alternatives, patients will fill this void through other means, some potentially turning to illegal opioids which could prolong the opioid epidemic (Martins et al, 2019).

Public service announcements have provided the general public with awareness of the dangers of opioids. This arguably is the first step in directing the patient to alternative treatment methods. However, since this awareness campaign, little has been done to create a multi-tiered

clinical approach to pain management and control. With the widespread need for pain management specialists, there are limited clinical resources to address the need.

Alternative treatments are being implemented; however, cost is a barrier and their effectiveness is still being evaluated. Much more clinical work needs to be done to address pain management treatment and control.

Opioid abuse cannot be simply legislated away. The solution to pain management and the reduction of addictive medications needs to happen at the clinical level and not at the legislative level. While legislation can work to support clinical solutions, legislation should not be driving clinical practice. For example, legislation to address the cost of alternative non-addictive pain medications would be extremely helpful, legislation restricting practitioner's treatment capabilities is not. A strong working synergy between practitioners and legislators with each understanding the role that the other plays, is instrumental to developing strong and effective healthcare policy.

Legislative action which regulates the insurance and pharmaceutical companies in the funding and development on non-addictive pain medications should be pursued. Currently, healthcare insurance companies pay for the lower cost opioid medications but may not approve the payment for the more expensive non-addictive alternatives (Medpac, 2019). Legislators routinely talk about the need for lower the cost of medications, payment for alternative non-addictive pain medications should be included in these discussions.

Legislators and law enforcement officials play an important role in the reduction of opioid use amongst the general population. Through more consistent national laws and stricter enforcement of current laws in eliminating the production, transportation, and distribution of

illegal opioids, the fight to reduce opioid addiction and deaths can only improve (Gross & Gordon, 2019).

Healthcare policy related to the elimination of opioid pain medications clearly requires a collaborative effort between Legislators, law enforcement, medical practitioners, pharmaceutical companies, and insurance companies to develop a comprehensive plan to combat the overuse and addiction to opioids.

Implications for Quality and Safety

In the trauma setting, practitioners prescribe opioid medications to provide the patient with relief from pain associated with the injuries they sustained. Pain medications are intended to improve the quality of life for the patient as they recover from their injuries. Practitioners adjust these medications at regular intervals as the patient's need require, and the patient's condition is routinely monitored for the effectiveness of the treatment. In this environment, flexibility in prescribing practices needs to be given to the practitioner so that the overall well-being of the patient is addressed.

As patients leave the hospital setting, practitioners in general have reduced or eliminated the administration of opioid medications for the control of pain with each patient to avoid the potential of the patient becoming addicted to opioids. However, some patients are prescribed opioids as they are the most effective treatment for their medical condition. As legislation restricts the patient from obtaining opioid medications, the recovering patient is inconvenienced through requiring multiple medical office visits in a week to obtain refills of the needed prescription. Illegally obtained pain medications are unregulated and as such their strength and active ingredients are generally unknown. Patients seeking relief may turn to the illegal marketplace for the convenience of obtaining medications (Martins et al, 2019). Illegal drug

confiscations occur regularly and often police officials describe these drugs to the public. In any given confiscation, these drugs have been combined with other compounds which change their potency and present increased danger.

Implications for Education

Patient education and awareness in general has been ongoing through public awareness campaigns. Patients in the hospital setting are made aware of the dangers of opioid usage through discussions with their medical team and literature contained in their discharge instructions. Patient education will continue into the foreseeable future until the opioid crisis is eradicated.

The results of this study have shown a statically significant reduction in the consumption of opioid pain medications in the inpatient trauma setting. The goal is to publish this study so that medical professionals are made aware of the effort and impact in reducing inpatient opioid use.

While there was a statically significant reduction in the overall consumption of opioid medications by the trauma patient population, the total of opioid deaths in New Jersey on a statewide basis increased by 32% (CDC, 2019). Education of the medical community should focus on the goal of contributing to the reduction in opioid use. The medical community can only control a small percentage of the cause and effect of opioid abuse and cannot impact the totality of opioid abuse because not all individuals with opioid addiction issues began their use from a given medical condition or through a prescription from a practitioner (National Institute on Drug Abuse, 2018). For this reason, education on the use of opioids must be a multifaceted approach.

Elected officials and law makers play a key role in combating opioid addiction. Stronger and more consistent effort must be placed on educating these officials in the clinical challenges

in treating opioid addiction. This education is not limited to the treatment of addicted patients, but also in the treatment of those who are addicted because of social or socioeconomic pressures. Both are important to treat, and each may require unique approaches in the treatment planning and program. The social aspects to opioid addiction are as important to understand and treat, as well as the addiction itself.

In many states, pharmacies are required to track certain medications to help reduce prescription drug abuse; however, these programs vary from state to state and may not report across state lines (PDMPTTAC, n.d.). Pharmacies should be included in the education and treatment planning of opioid use and abuse.

Economic Implications

Opioid medications have proven to be a minimal first cost medication in that the cost of the medication is inexpensive, alternative medications and treatments have a much higher first cost making them less practical to employ on a widescale basis. However, as we are now learning with the associated addiction issues, the long-term cost of opioid prescriptions can cost considerably more.

The highest price paid for opioid addiction is the loss of life. If the medical practitioner can prevent addiction from occurring through prescribing alternative treatment methods, the impact to the injured patient and their family can be enormous. It is tragic enough for a patient and their family to experience the traumatic event, it is even more tragic for that same patient and family to then have to deal with the effects of an opioid addiction. Medical practitioners are working tirelessly to find alternatives to adequately treat the traumatically injured patient and to prevent future complications.

The cost to treat a patient for substance abuse is extremely expensive. Many insurance plans cover portions of addiction treatment but rarely cover the entire cost. In many cases treatment for opioid addiction is financially devastating for the patient and their family. This is in addition to the emotional price paid by the patient and their family members. Through awareness and education, if practitioners are able to play a role in reducing the use of opioids through prescribing alternative non-addictive remedies, the overall economic impact to the medical community will be significant.

Sustainability and Professional Reporting

This project focused on two calendar years of patient information to study the impact of legislation aimed at reducing the use of opioids in the State of New Jersey. While the results of this study showed a significant reduction in the consumption of opioids in the inpatient setting, this reduction did not translate to a reduction in deaths attributed to the current opioid crisis. For this reason, this study should continue through review of subsequent years of data to determine if there will be a long-term impact and correlation between a reduction in prescribed opioid medications and deaths.

The results of this study are planned to be published in a peer reviewed journal. Through publishing the results of this study, medical professionals can use the results to drive policies and best practices in their own organizations. Pain management is a growing and evolving practice, through studies such as this, institutional best practice guidelines can be formulated to improve patient care and positively impact the financial cost of patient treatment.

Pain management and more specifically the treatment for pain is not widely understood in the professional clinical setting. There are scattered pain management practitioners working in practice to improve the quality of life for those suffering from chronic pain. However, only

recently has there been more of an emphasis put towards the study and treatment of pain. Clinically, educational institutions should develop programs for the study of pain management and information for the treatment of pain should be imparted on clinical professions throughout their formal training. in addition, as more is understood about pain and pain management, standard practice guidelines could be developed to provide a more prescriptive approach to improve the quality of life for those suffering from chronic pain.

Conclusion

The inspiration of this study was the awareness of the opioid crisis and the impact it posed to society. For most medical professionals, their driving motivation is to help people in crisis and to promote healing. To that end, trauma medical professionals understood the impact opioids were having on their patient population and began exploring alternative pain treatments at the time the legislation was enacted. The results of this study demonstrated a positive change in clinical behavior on the part clinical practitioners as they strived to do their part in stemming the tide of the exponentially growing opioid epidemic.

This study also illustrated that the legislation alone did not and has not corrected the problem of reducing the number of opioid related deaths. It is logical to conclude that a single piece of legislation cannot correct a systemic societal problem. While the alternative measures taken by practitioners in the inpatient setting have gone a long way to contributing to a reduction in prescribed opioid medications, the aftercare treatment of all patients is still lacking if the effort to reduce opioid deaths is to be successful.

Once again, this demonstrates that one single entity cannot correct a multi-tiered societal problem. Medical professionals, legislators, law enforcement, community leaders, and the

community itself must work in a collaborative fashion to employ meaningful and multifaceted solutions to solve this crisis.

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Appendix A

EBP Question: For adult patients 18-89 years of age admitted to the hospital trauma service, has the legislation limiting the use of opioid prescriptions for acute pain changed the prescribers practice in the hospital setting?
Date: May 12, 2019

Article #	Author & Date	Evidence Type	Sample, Sample Size, Setting	Study findings that help answer the EBP Question	Limitations	Evidence Level & Quality
1	Bugaev, N. 2016-Journal of Trauma and Acute Care Surgery	Retrospective review	Level 1 trauma center; 16 years and older admitted with blunt rib fracture(s); 245 patients	Number of rib fractures and amount of displacement were identifiers of opioid requirements.	Retrospective review; small cohort; single person measured all rib fracture displacements; pain scores were not recorded in database; scattered history of narcotic use.	III-B
2	Carrie, C. 2017-Anaesthisia Critical Care Pain Management	Retrospective case-control study	Level I trauma center in France; patients with multiple rib fractures; 357 patients admitted with 3 or more rib fractures; 69 pairs of patients before and after the intro of the bundle of care.	Multidisciplinary pathway is doable in the emergency setting and significantly improves pain control after ED management through increased use of NSAIDs and regional anesthesia.	small sample size due to restrictive inclusion criteria; matched on age and Thoracic Trauma Severity score which showed the best predictive ability for the development of post-traumatic complications and mortality.	III-B

3	Chaudhary, M.A. 2017-JAMA Surgery	National cohort	33,762 opioid-naïve trauma patients who were beneficiaries of Military Heath Insurance and were treated at both military and civilian hospitals between 2006-2013.	Opioids are being prescribed appropriately for injury severity and level of pain.	Data lacks clinical information such as pain severity, in-hospital opioid use, and rational for opioid prescription. Data limited access to multimodal pain management strategies. Study population specific to military and may not be generalizable to US population as a whole.	III-B
4	Curtis, K. 2016-Australiasian Emergency Nursing Journal	Retrospective review pre-post cohort study	546 participants with blunt chest injury; 273 before chest injury protocol (ChIP); 273 post ChIP; level I trauma center in Australia	Chest injury protocol reduced rate of pneumonia and improved delivery of care in patients with isolated chest trauma.	Barriers to implement protocol were lack of time, lack of resources, poor access to guidelines, lack of continuing education, and preconceived opinions. Retrospective review.	III-B
5	Davis, C.S. 2019-Drug and Alcohol Dependence	Systematic, multi-source legal review	50 states that impose mandatory limits on the amount and duration of opioid prescriptions	To date, there is no data on whether these laws mediate opioid-related morbidity and mortality.	Only examined states that limited prescription or dispensing of opioids for acute pain. Analysis does not capture variations in prescription deviations due to permitted deviations.	III-B

6	Dhillon, T.S. 2015-Journal of Trauma and Acute Care Surgery	Cohort study; prospective planned secondary analysis randomized trial	Level I trauma center; 280 parent randomized trial; 244 traumatic chest wall injury; 189 evaluated for outcomes	Predicts increased patient perceptions of pain and physical limitations. Especially lower rib fractures which also predicts respiratory symptoms	# fractured ribs, chest AIS score, prescience of flail chest are not perfect measures of chest wall injury severity; follow-up at 60 days may be too soon to identify complications; outcome measures not specifically designed for trauma patients	II-B
7	Esmailian, M. 2015-Emergency	Double-blind clinical trial (RCT)	54 patients; 18 years of age and older; two educational hospitals in Iran	IV acetaminophen and morphine are equal in relieving rib fracture pain	Small sample size; lack of placebo	I-B
8	Fabricant, L. 2013-The American Journal of Surgery	Prospective observation	Level 1 trauma center, 203 inpatients with rib fractures were included (enrollment within 14 days of injury), 16 years of age and older.	Prolonged rib fracture pain and disability is common after rib fractures.	Heterogeneity of injured population; no screening of pre-existing pain syndromes or narcotic use.	III-C

9	Flarity, K. 2017-The American Surgeon	Retrospective cohort study	Level II trauma center; admitted patients 18 years and older with one or more rib fractures; 48 month study period; 571 patients (252 pre and 319 post-intervention)	Decrease in ICU LOS over 2 days; Improved outcomes and cost effective care	Single center study; May not be generalizable; May not be reflective of general population; Statistically significant but not clinically relevant; Coding and diagnosis inaccuracies (retrospective cohort)	III-B
10	Hanson, R.N. 2017 Current Medical Research	Retrospective review	61,017 cholecystectomy patients	Addition of IV acetaminophen to perioperative pain management decreased LOS, and reduced opioid use.	Retrospective review	III-B
11	Karamchandani, K. 2019-Journal of Trauma and Acute Care Surgery	Narrative review	N/A	Recommend use of non-opioid analgesics, regional anesthesia, and other opioid sparing modalities to improve management of pain in critically injured patients.	Literature review	III-B

12	Marasco, S. 2015-Injury	Retrospective review	Trauma hospital in Australia; 397 admitted over a five year period with rib fractures (not treated with fixation);	Significant reduction of quality of life for patient who sustain rib fractures 24 months post injury (6 months return to work rates low, 60% reported a significant reduction in function at 24 months post rib fracture(s)); need more effective interventions for these patients	Retrospective review	III-B
13	O'Neal, J.B. 2017-The Journal of Arthroplasty	Randomized, double-blinded, placebo-controlled clinical trail	174 randomized post total knee arthroplasty to one of 3 groups (IV acetaminophen 57), (oral acetaminophen 58), (placebo 59).	Neither IV or PO acetaminophen provide additional analgesia in the immediate post-op period.	Lack of standardization for pre and post op care	I-C
14	Oyler, D.R. 2015-Journal of Trauma and Acute Care Surgery	Literature review	Searched MEDLINE, CINAHL, Web of Science, Scopus, WorldCat, and International Pharmaceutical Abstracts databases	Use of early multiple nonopioid adjuncts may decrease or eliminate opioid use for traumatic pain thus decreasing potential opioid dependence.	Literature review	V-A

15	Oyler, D.R. 2018-American Journal of Health-System Pharmacy	Electronic cross-sectional survey	Academic medical center; 363 completed the survey (153 attending physicians, 67 resident physicians, 98 pharmacists, and 46 advanced practice providers).	Prescribers believe opioids are overused in this academic setting to satisfy patients and providers are uncomfortable prescribing non-opioid analgesics for patients.	Response to survey was only 25.1%; only represents a single medical center and may not be generalizable to other types of medical centers.	III-B
16	Oyler, D. 2018-American Journal of Health-System Pharmacy	Retrospective post study review	489 admitted with acute trauma before 424 after project implementation. Academic hospital	Targeted education reduces milligram morphine equivalents on discharge.	National and local initiatives may have exaggerated the effect on study interventions. Retrospective review. A priori power analysis or sample size calculation was not conducted allowing the possibility of a Type I error.	III-B
17	Romeiser, J.L. 2019-Drug and Alcohol Dependence	Retrospective review	1440 overdose mortalities and 26.8 million opioid prescriptions throughout NY state in 2013-2015.	Reducing the number of prescriptions may not be effective in reducing prescription related mortality.	Lack of available dosing data and detailed rates for each opioid were not provided.	III-B

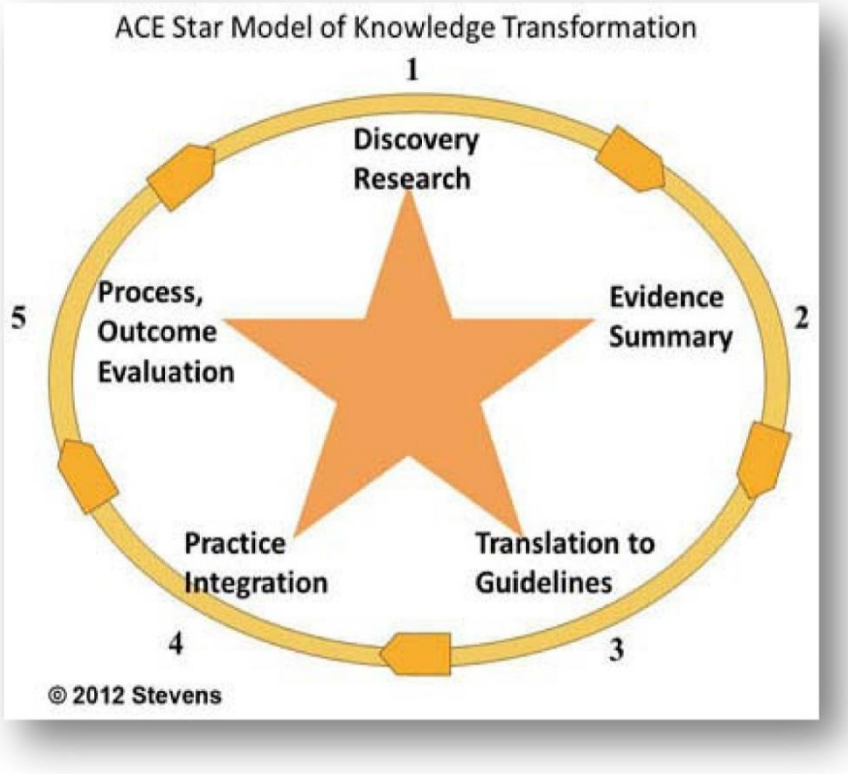
18	Sahr, S.M. 2013-Journal of Trauma Nursing	Retrospective review	Level 1 trauma center; admitted patients 65 years and older with at least 1 rib fracture; 4 years divided into 2 periods (pre and post protocol); 81 pts in pre-protocol and 67 in post-protocol	Patients 65 years and older benefit from a standardization of care by reducing LOS in the more seriously injured patient.	Small sample size; single institution; may not be generalizable to other populations; retrospective study.	III-B
19	Sun, L. 2018 Medicine	Systematic review and meta-analysis	N/A	IV acetaminophen to multimodal pain meds does not demonstrate significant benefit in reducing pain compared to oral acetaminophen	Literature review	V-B
20	Unsworth, A. 2015-Scandinavian Journal of Trauma	Literature review	MEDLINE, EMBASE, CINAHL, and the Cochran library were searched using a structured clinical question.	Clinical pathways, epidural analgesia, and rib fixation improve ICU and hospital LOS as well as morbidity and mortality in patients with blunt chest trauma.	Literature review. All literature was not included in this review related to treatment of rib fractures.	V-B

21	Whitmore, C.C. 2019-Preventative Medicine Reports	Qualitative review	10 states with prescription monitoring programs	Remains need for research to address the evolution of the opioid epidemic to inform and develop comprehensive policy solutions.	Used a subset of states limiting generalizability and cheaper illicit opioids making it difficult to anticipate addition legislation in this rapidly changing environment.	III-B
22	Witt, C.E. 2017-Trauma Surgery & Acute Care Open	Review	N/A	Recommend a standardized management algorithm for patients with rib fractures.	Review rib fracture protocol and outcomes.	V-B
23	Yang, L. 2017-International Journal of Surgery	Systematic review and meta-analysis	316 studies meta-analysis; 3 RCT and 1 Non-RCT; 534 pts in acetaminophen group; 331 patients in control group	Acetaminophen to multimodal analgesia could significantly reduce pain and opioid use.	4 articles included in study (1 which was retrospective); Could not perform meta-analysis due to insufficient relevant data; Methodological weaknesses; Duration of follow up was relatively short (complication underestimation); Publication bias in previous meta-analysis	II-B

Appendix B

ACE Star Model of Knowledge Transformation

- Research opioid epidemic in the US
- Review relevant literature
- Apply for IRB approval at [redacted] to query 2 years of data from the trauma data base (2016 and 2018)



- Create an evidence table summarizing literature
- Develop screening criteria
- Query trauma database information consistent with criteria

- Review results of data screening
- Summarize results

- Review results with physicians
- Post project and provide a presentation to leadership and the physicians

- Document results of retrospective review
- Publish results in a peer reviewed journal.

Stevens, K. R. (2012). *Star Model of EBP: Knowledge Transformation.* Academic Center for Evidence-based Practice The University of Texas Health Science Center at San Antonio. Retrieved from http://nursing.uthscsa.edu/onrs/starmodel/star-model.asp

Appendix C

Letter of Cooperation

March 26, 2018

Letter of Cooperation for Medical Center

Dear Renay Durling-Grover,

This letter confirms that that I, as an authorized representative of the Medical Center allow the Principal Investigator access to conduct study related activities at the listed site, as discussed with the Principal Investigator and briefly outlined below, and which may commence when the Principal Investigator provides evidence of IRB approval for the proposed project.

Research Site(s): Medical Center in NJ

Study Purpose: The focus of this project is directed to the traumatically injured patients and the methods used to address and control their pain. This retrospective review will study the medications used in pain management practices for the trauma patient prior to (2016), and since the enactment of New Jersey Senate Bill 3 (2018) which restricts the use of opioids. The aim of this project is to evaluate the impact of recently passed legislation regarding the restriction of opioid prescriptions and its effectiveness in reducing the use of opioids in the treatment of pain for the trauma patient.

Study Activities: Query the trauma database to retrospectively review the opioid requirements of patients with traumatic injuries admitted to the trauma service.

Subject Enrollment: Trauma patients 18-89 years of age admitted to the medical center with traumatic injuries. The target enrollment is 1500-2000 patients. This study is a retrospective review using the trauma database and patient records from 2016 and 2018 who were treated with opioids.

Site(s) Support: Access to information in the trauma database (DI V5 Trauma Registry) will be provided once the PI receives IRB approval. There is support available at the medical center from a PhD Nurse Researcher as well as a PhD Research Scientist in the Department of Surgery.

Data Management: Protection and confidentiality will be maintained throughout the duration of the research project. Data collection will be kept on the medical center's computers only and all data will be de-identified. Data will be stored on the medical center's servers for 2 years after the research article has been published.

Anticipated End Date: This retrospective review will study the medications used in pain management practices for the trauma patient prior to (2016), and since the enactment of New Jersey Senate Bill 3 (2018) which restricts the use of opioids.

We understand that this site's participation will only take place during the study's active IRS approval period. All study related activities must cease if IRB approval expires or is

understand that any activities involving Personal Private Information or Protected Health Information may require compliance with HIPAA Laws and Rutgers Policy.

Our organization agrees to the terms and conditions stated above. If we have any concerns related to this project, we will contact the Principal Investigator. For concerns regarding **IRB** policy or human subject welfare, we may also contact the Rutgers IRB (see orra.rutgers.edui/hspp).

Regards,

Signature	**Date Signed**
[redacted]	Director of Trauma/Surgical Critical Care **Job Title** 3/26/2018
	Date Signed
	Director of Trauma/Surgical Critical Care

Appendix D

NURSING RESEARCH COUNCIL

APPROVAL LETTER

Date: March 26, 2018

TITLE A Review of Opioid Use for Pain in Adult Patients with Traumatic Injuries

INVESTIGATOR Renay Durling Grover, MSN, RN, CEN

CO-INVESTIGATOR(S)

TYPE OF REVIEW Expedited {X} Full { }

TYPE OF APPROVAL New {X} Revision { }

ITEMS APPROVED: Protocol {X} Dated
Consent { } Dated _____
Recruitment Tools { }

FOR FULL REVIEW:

NURSING RESEARCH COUNCIL PRESENTATION DATE:
REVIEWED BY:
REVIEWED BY:

The Nursing Research Council at the Medical Center has reviewed the above Research Proposal per the Criteria for Review of Research Proposals.

ACTION: {X} Approved { } Approved Pending Changes Review { } Not Approved

[redacted]

[redacted]

Appendix E

Site Institutional Review Board

TO: Renay Durling-Grover, RN, MSN, CEN

PROJECT TITLE: [1191052-1] A Review of Opioid Use for Pain in Adult Patients with Traumatic Injuries

SUBMISSION TYPE: New Project

ACTION: APPROVED

REVIEW DATE: March 16, 2018

APPROVAL DATE: March 27, 2018

EXPIRATION DATE: N/A

REVIEW TYPE: Expedited Review

NUMBER OF APPROVED CONSENT FORMS: *[0]*

REVIEW CATEGORY: Expedited review category # *[5]*

HIPAA:

☐	Obtain Authorization	☒	Waiver of HIPAA Authorization
☐	Obtain Consent	☒	Waiver of Consent
☐	Alteration of Consent	☐	Waiver of Documentation of Consent

The submission reviewed for above-referenced protocol has received approval based on applicable federal regulations.

No investigator involved in the above referenced protocol participated in the vote to approve the study.

The following items were reviewed with this submission:

- Application Form - Initial Review.pdf (UPDATED: 01/31/2018)
- Cover Sheet - Study Personnel Form.pdf (UPDATED: 03/26/2018)
- Data Collection - Retrospective Chart Review.pdf (UPDATED: 03/26/2018)
- HIPAA Waiver - Waiver.pdf (UPDATED: 01/31/2018)
- Investigator Agreement - DH IA Ribs.pdf (UPDATED: 01/31/2018)
- Investigator Agreement - RDG IA Ribs.pdf (UPDATED: 01/31/2018)

- Investigator Agreement - ZN IA Ribs.pdf (UPDATED: 01/31/2018)
- Investigator Agreement - LD IA Ribs.pdf (UPDATED: 01/31/2018)
- Protocol - Retrospective research protocol rib fracture opioid final.pdf (UPDATED: 03/26/2018)
- Training/Certification - Nursing Research Council Approval Letter.pdf (UPDATED: 03/26/2018)
- Training/Certification - Signed Dept Chair Cert.pdf (UPDATED: 01/30/2018)

The following items were approved with this submission:

- Cover Sheet - Study Personnel Form.pdf (UPDATED: 03/26/2018)
- Protocol - Retrospective research protocol rib fracture opioid final.pdf (UPDATED: 03/26/2018)
- Training/Certification - Signed Dept Chair Cert.pdf (UPDATED: 01/30/2018)

Report all events that are unanticipated problems, unanticipated problems, which are also adverse events, deaths occurring in subjects enrolled at an AHS facility, and deviations from the approved protocol that would place the subject at greater risk than anticipated, to the AHS IRB in writing immediately.

The Food and Drug Administration Amendment Act of 2007 requires that Phase II-IV trials of drugs and biologics and trials of devices be registered in ClinicalTrials.gov. The responsibility of registering these trials falls on the sponsor of the trials and/or the Principal Investigator. If you are conducting an "Investigator-initiated" study that fits the criteria above, you must register. If you are conducting a sponsored trial fitting the criteria, you must ensure that the sponsor registers.

Modifications to the study must be submitted in writing and approved by the IRB prior to implementation of the changes.

Investigators are required (by Federal Regulations) to submit reports on the status and/or results of clinical studies approved by the AHS IRB. For the above-referenced study, status/result reports will be due on the basis indicated above and/or within 30 days of the termination of the investigation. It is the Principal Investigator's responsibility to secure continuing approval or notify the IRB of termination of the study.

No subjects may be enrolled into this study after the above expiration date unless a continuation report is submitted and approved by the IRB.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within IRB's records.

Appendix F

Site Institutional Review Board Continuing Review

TO:	Renay Durling-Grover, RN, MSN, CEN
PROJECT TITLE:	[1191052-2] A Review of Opioid Use for Pain in Adult Patients with Traumatic Injuries
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	March 27, 2019
EXPIRATION DATE:	N/A
REVIEW TYPE:	Expedited Review

The submission reviewed for above-referenced protocol has received approval based on applicable federal regulations.

No investigator involved in the above referenced protocol participated in the vote to approve the study.

The following items were reviewed with this submission:

- Amendment/Modification – Reportable New Information.pdf (UPDATED: 03/25/2019)
- Continuing Review/Progress Report – Research Status Report.pdf (UPDATED: 03/25/2019)
- Other – Study Personnel 2019.pdf (UPDATED: 03/25/2019)

The following items were approved with this submission:

- Other – Study Personnel 2019.pdf (UPDATED: 03/25/2019)

Report all events that are unanticipated problems, unanticipated problems, which are also adverse events, deaths occurring in subjects enrolled at an AHS facility, and deviations from the approved protocol that would place the subject at greater risk than anticipated, to the AHS IRB in writing immediately.

Title VIII of the Food and Drug Administration (FDA) Amendment Act of 2007 (FDAAA) expanded the legal mandate for sponsors and other responsible for certain clinical trials to register their studies and report summary results information to ClinicalTrials.gov. The responsibility of registering falls on the study sponsor or the Principal Investigator. If you are conducting an "Investigator-initiated" study, you must verify whether or not the study meets the criteria to register. If you are conducting a sponsored clinical trial, you must confirm that the sponsor registers.

Modifications to the study must be submitted in writing and approved by the IRB prior to implementation of the changes.

Investigators are required (by Federal Regulations) to submit reports on the status and/or results of clinical studies approved by the AHS IRB. For the above-referenced study, status/result reports will be due on the basis indicated above and/or within 30 days of the termination of the investigation. It is the Principal Investigator's responsibility to secure continuing approval or notify the AHS IRB of termination of the study.

No subjects may be enrolled into this study after the above expiration date unless a continuation report is submitted and approved by the IRB.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within IRB's records.

Appendix G

Rutgers Institutional Review Board Approval

RUTGERS eIRB

Arts & Sciences IRB - New Brunswick
335 George Street
Suite 3100, 3rd Floor
New Brunswick, NJ 08901
Phone: 732-235-2866

Health Sciences IRB - New Brunswick/Piscataway
335 George Street
Suite 3100, 3rd Floor
New Brunswick, NJ 08901
Phone: 732-235-9806

Health Sciences IRB - Newark
65 Bergen Street
Suite 511, 5th Floor
Newark, NJ 07107
Phone: 973-972-3608

DHHS Federal Wide Assurance Identifier:
FWA00003913

IRB Chair Person: Cheryl Kennedy

IRB Director: Carlotta Rodriguez

Effective Date: 8/6/2019

Approval Date: 6/18/2019

Expiration Date: 3/27/2020

eIRB Notice of Administrative Review # Pro2019001056

STUDY PROFILE

Study ID: Pro2019001056

Title: A Review of Opioid Use for Pain in Adult Patients with Traumatic Injuries

Principal Investigator:	Mary Kamienski	**Study Coordinator:**	Renay Durling-Grover
Co-Investigator(s):	Renay Durling-Grover	**Approval Cycle:**	Other
Risk Determination:	Minimal Risk	**Review Type:**	Administrative Review

CURRENT SUBMISSION STATUS

Submission Type:	Administrative Review (for NCI-CIRB, Commercial or other non-Rutgers IRB Review Request)	**Submission Status:**	Approved
Approval Date:	6/18/2019	**Expiration Date:**	3/27/2020

Pregnancy Code:	No Pregnant Women as Subjects	**Pediatric Code:**	No Children As Subjects	**Prisoner Code:**	No Prisoners As Subjects

Other Materials: [redacted] System IRB approval dated March 27, 2019
[redacted] System / Rutgers University IRB IAA

*** Study Performance Sites:**

Rutgers University, Newark, NJ

[redacted] NJ

ALL APPROVED INVESTIGATOR(S) MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. **Continuing Review:** Approval is valid until the protocol expiration date shown above. To avoid lapses in approval, submit a continuation application at least eight weeks before the study expiration date.

3. **Expiration of IRB Approval:** If IRB approval expires, effective the date of expiration and until the continuing review approval is issued: **All research activities must stop unless the IRB finds that it is in the best interest of individual subjects to continue. (This determination shall be based on a separate written request from the PI to the IRB.) No new subjects may be enrolled and no samples/charts/surveys may be collected, reviewed, and/or analyzed.**

4. **Amendments/Modifications/Revisions**: If you wish to change any aspect of this study, including but not limited to, study procedures, consent form(s), investigators, advertisements, the protocol document, investigator drug brochure, or accrual goals, you are required to obtain IRB review and approval prior to implementation of these changes unless necessary to eliminate apparent immediate hazards to subjects.

5. **Unanticipated Problems**: Unanticipated problems involving risk to subjects or others must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: https://orra.rutgers.edu/hspp

6. **Protocol Deviations and Violations**: Deviations from/violations of the approved study protocol must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: https://orra.rutgers.edu/hspp

7. **Consent/Assent**: The IRB has reviewed and approved the consent and/or assent process, waiver and/or alteration described in this protocol as required by 45 CFR 46 and 21 CFR 50, 56, (if FDA regulated research). Only the versions of the documents included in the approved process may be used to document informed consent and/or assent of study subjects; each subject must receive a

copy of the approved form(s); and a copy of each signed form must be filed in a secure place in the subject's medical/patient/research record.

8. **Completion of Study:** Notify the IRB when your study has been stopped for any reason. Neither study closure by the sponsor or the investigator removes the obligation for submission of timely continuing review application or final report.

9. The Investigator(s) did not participate in the review, discussion, or vote of this protocol.

Appendix H

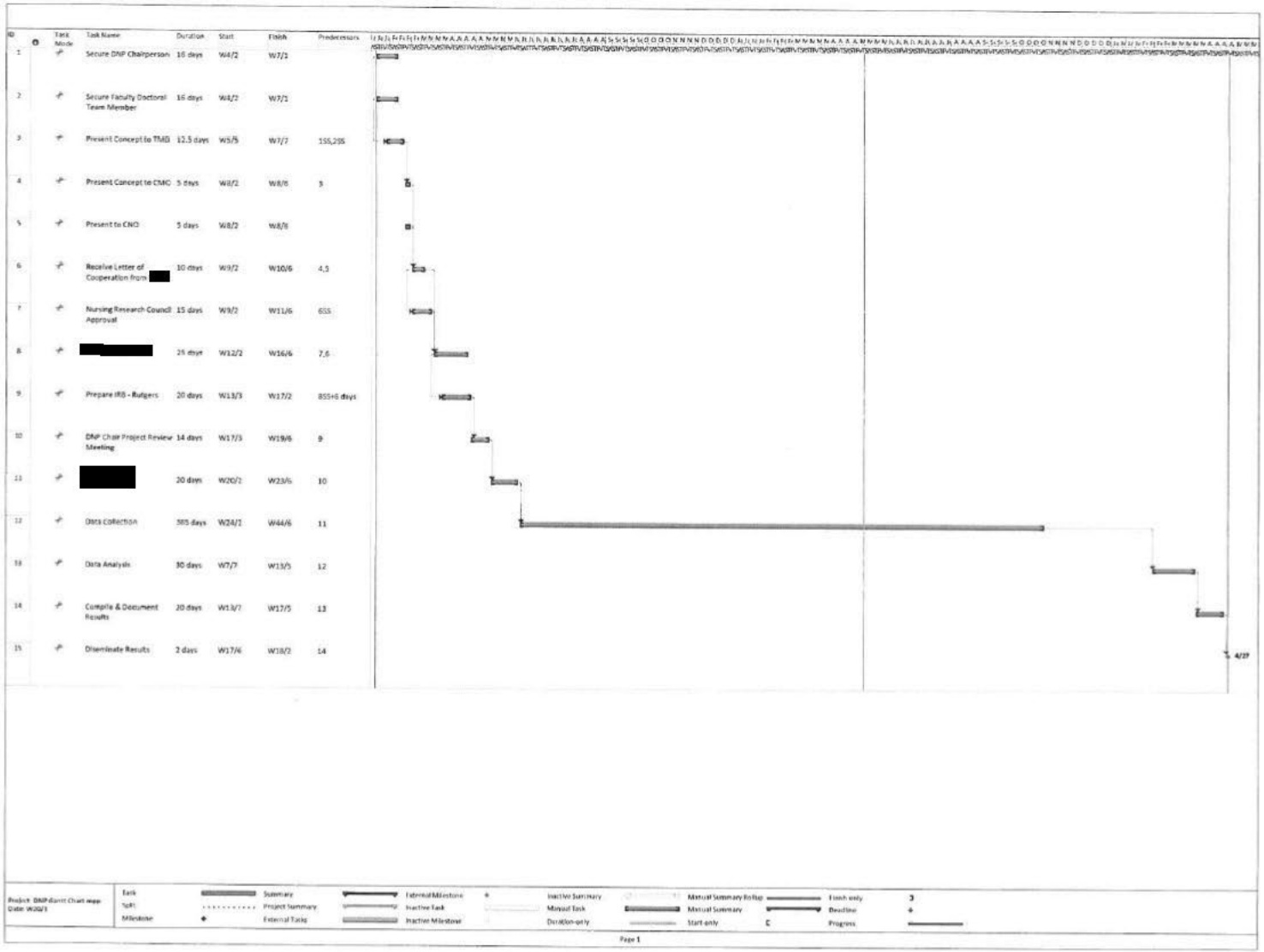
A Review of Opioid Use for Pain in Adult Patients with Traumatic Injuries

Data Points

Trauma Number
Age
Race
ED Disposition
Trauma Response Level
ISS
Length of Stay in Days
Length of Stay in Hours
Admitting Service
ICD 10 Codes
Mechanism of Injury
Hospital Disposition
Arrival time
Arrival date
Discharge time
Trauma Transfer
Name of Opioid Administered
Amount of Opioid Administered per Day
Opioid Administered Converted to IV Morphine Dose
PCA pump (Yes/No)
Amount of Opioid in PCA Pump Administered per Day
Opioid Administered through Pump Converted to IV Morphine Dose

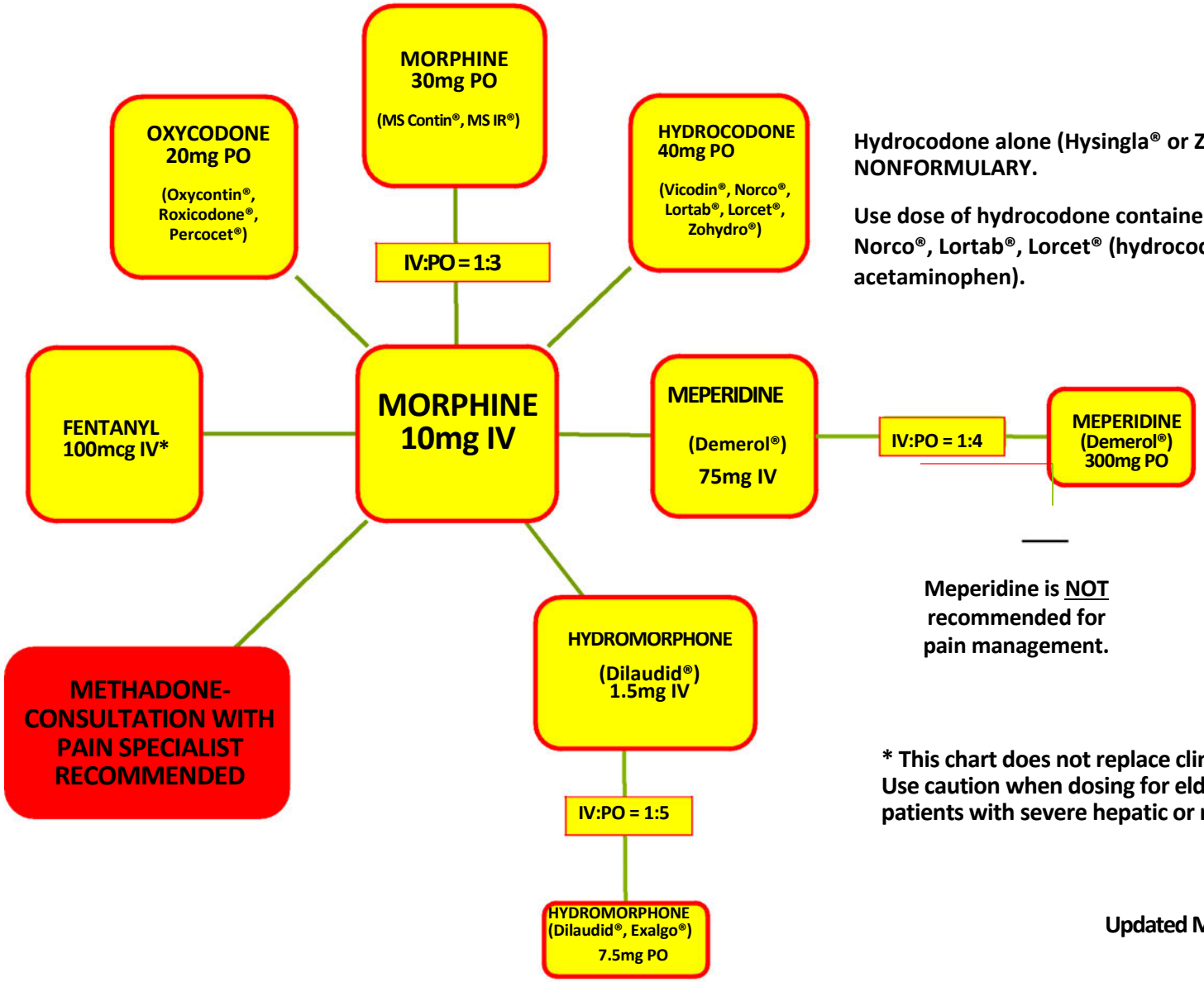
Appendix I

Gantt Chart



Appendix J

ADULT Narcotic Conversion Reference



Hydrocodone alone (Hysingla® or Zohydro®) is NONFORMULARY.

Use dose of hydrocodone contained in Vicodin®, Norco®, Lortab®, Lorcet® (hydrocodone / acetaminophen).

Meperidine is NOT recommended for pain management.

*** This chart does not replace clinical decision-making. Use caution when dosing for elderly patients or patients with severe hepatic or renal disease.**

Updated March 2017

Appendix K

ADULT Narcotic Conversion Spreadsheet

Day	Opioid Name	Conversion Factor	Opioid Dose (mg)	Converted to morphine IV	Number of doses	Total amount of opioid given
	1-Fentanyl IV		*fentanly in mcg*			
	2-Hydrocodone PO					
	3-Hydromorphone IV					
	4-Hydromorphone PO					
	5-Morphine IV					
	6-Morphine PO					
	7-Oxycodone PO					
	8-Codeine					
	9-Tramadol					
	10-Fentanyl (patch)					
		#N/A		#N/A		#N/A
		#N/A		#N/A		#N/A
		#N/A		#N/A		#N/A
		#N/A		#N/A		#N/A
		#N/A		#N/A		#N/A
		#N/A		#N/A		#N/A
		#N/A		#N/A		#N/A
		#N/A		#N/A		#N/A
		#N/A		#N/A		#N/A
		#N/A		#N/A		#N/A

Average amount of opioid/day	Total amount of opioid in entire stay
#DIV/0!	0
MGs of tylenol	
Doses of tylenol	
Total	0
# of days tylenol given	
Avg/day	#DIV/0!

Total amount of opioid per each postop day													
1	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
2	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
3	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
4	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
5	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
6	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
7	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
8	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
9	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
10	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
11	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
12	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
14	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
15	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
16	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
17	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
18	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
19	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
20	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
21	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

*only goes up to 21 Days
*only goes up to row 60
*average amount of opioid per day divides the total amount of opioid given by the last day they were given opioid