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Creating An Integrated Opioid Policy For Multi-State Hospice Practices: Improving Opioid Compliance And Patient Safety

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CREATING AN INTEGRATED OPIOID POLICY FOR MULTI-STATE HOSPICE PRACTICES: IMPROVING OPIOID COMPLIANCE AND PATIENT SAFETY

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This DNP Project is accepted in partial fulfillment of the requirements for the degree Doctor of Nursing Practice.

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Signed: _____

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Abstract

End of life (EOL) symptom management is the cornerstone of hospice care. Hospice patients, especially advanced cancer patients, have an increased need for pain and symptom management towards end of life. For those patients at EOL, opioids are the mainstay treatment to relieve intractable and breakthrough pain. Due to opioid regulatory changes over the past few years, there has been more confusion than clarity among the hospice & palliative care practitioners prescribing opioids for EOL pain management. Healthcare practices across the country are realigning their policies to the opioid prescription rule changes. It is imperative for hospice providers to translate federal and state opioid regulations into organizational policy to guide hospice & palliative care practice. The purpose of this project was to review, synthesize and reconcile federal, state, and local opioid regulations and create a system for a sustainable data base in order to develop and maintain opioid policies for implementation in multi-site hospice organization, across 35 states, to ensure ongoing compliance with opioid laws. The cyclic process of the KTA framework was used for the project that places creators and users within a system which is dynamic as well as adaptive, so that as the opioid regulations change, the policy and protocols will be modified and re-adopted. An umbrella opioid medication policy, and state specific guidance was developed. Results show that, 4 weeks after policy dissemination, 32 out of 35 states continued to maintain 100% clinician compliance with the umbrella opioid medication policy, and state specific guidance. There was a 50% reduction in opioid-related events. This DNP project has applicability to further compliant opioid practice in a variety of care settings nationwide.

Keywords: End of life, Hospice, Opioid, Pain, Regulatory Compliance.

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Glossary

Term	Definition
Abuse (Opioid)	A problematic pattern of opioid use (CDC, 2019)
Addiction (Opioid)	A major health problem characterized by increasing drug tolerance and compulsive urge to take opioid medication
AVP	Assistant Vice President
CDC	Centers for Disease Control and Prevention
CINAHL	Cumulative Index of Nursing and Allied Health Literature
DEA	Drug Enforcement Administration
Diversion (Opioids)	Illegally acquiring and using opioids (CDC, 2019)
EMR	Electronic Medical Record
EOL	End-of-life
HHS	The U.S. Department of Health and Human Services
KTA	The Knowledge-to-Action conceptual framework
MAT	Medication-assisted treatment for substance use disorders
Misuse (Opioid)	Use of illegal drugs and/or the use of prescription drugs in a manner other than as directed by a doctor or using someone else's prescription (CDC, 2019)
MME	Morphine Milligram Equivalents
PDMP	Prescription drug monitoring program
Pill-Mill	A clinic prescribing or dispensing controlled substance drugs inappropriately
RDCO	Regional Director of Clinical Operations
SAMHSA	Substance abuse and mental health services administration
SUD	Substance use disorder is a medical condition where use of one or more substances leads to a clinically significant impairment
SUPPORT	Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act
SVP	Senior Vice President
U.S.	United States
VP	Vice President
WHO	World Health Organization
Withdrawal (Opioids)	Acute unpleasant symptoms caused by stopping the use of opioids after heavy use of few weeks or after chronic use

Creating an integrated opioid policy for multi-state hospice practices: improving opioid compliance and patient safety

CHAPTER 1

Introduction

End of life (EOL) symptom management is the cornerstone of hospice care. Hospice patients, especially advanced cancer patients, have an increased need for pain and symptom management towards end of life. Increasingly, care of advanced cancer patients, palliative or hospice care, is being moved to ambulatory care settings, making it even more challenging to manage the symptoms of dying patients . For those patients at EOL, opioids are the mainstay treatment to relieve intractable and breakthrough pain. Due to opioid regulatory changes over the past few years, there has been more confusion than clarity among the hospice & palliative care practitioners prescribing opioids for EOL pain management. Healthcare practices across the country are realigning their policies to the opioid prescription rule changes. It is imperative for hospice providers to translate federal and state opioid regulations into organizational policy to guide hospice & palliative care practice.

Background

Uncontrolled pain is one of the most debilitating symptoms at EOL which affects 50% of the patients in their last month of life (Dy, 2016). Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (IASP, 2017). Acute pain is defined as the pain that comes on quickly, can be severe, but lasts a relatively short time, such as days to less than a few months. Chronic pain is defined as the pain that can range from mild to severe, and persists or progresses over a long period of time, such as over 3 months to several years. Breakthrough pain is a sudden increase in

pain that may occur in patients who already have chronic pain from cancer, arthritis, fibromyalgia, or other conditions. It usually lasts for a short time, but the level of pain may be severe. Breakthrough pain is usually not a symptom of a new condition or a condition that has gotten worse. It is also called pain flare (NCI, n.d.).

A recent review of patient safety and end of life reports that common safety issues in hospice and palliative care include inappropriate pain medications and inadequate pain management (Dy, 2016). Hospice patients have an increased need for pain and symptom management towards end of life. An additional challenge, especially for hospice providers, is breakthrough pain in cancer patients toward end of life. This sudden eruption of severe pain in a patient whose pain is otherwise adequately controlled on a long-acting pain medication can interrupt a terminally ill patient's daily life causing physical & psychological stress due to increased health burden, loss of independence and disrupted autonomy (Katz, Gajria, Shillington, Stephenson & Harshaw, 2017) leading to a decline in quality of life.

The goal of hospice is to provide comfort to the patient. Opioids are the mainstay treatment to relieve distressing EOL symptoms, such as intractable nausea and vomiting, dyspnea, cancer pain, and delirium. In a systematic review(Brant, Rodgers, Gallagher, & Sudaramurthi, 2017), it was found that opioids are the most effective and safe evidence-based pharmacologic treatment for adequate management of breakthrough cancer pain. Opioids are a substance used to treat moderate to severe pain. Opioids are like opiates, such as morphine and codeine, but are not made from opium. Opioids bind to opioid receptors in the central nervous system and block pain messages from body to the brain (NCI, n.d.). In spite of increasing regulatory scrutiny of opioid prescriptions and use, opiates are desirable and effective options for managing physical pain in terminally ill patients (Albert, 2017).

History of Opioid Prescription in United States

Pain treatment in the United States (U.S.) has evolved over the years. In later part of the 19th century morphine was used to treat pain symptoms in those injured in Civil War. Similarly, anesthetics and analgesics were prescribed to manage pain in war veterans during early 20th century (Bernard, Chelminski, Ives, & Ranapurwala, 2018). In the last 50 years, the U.S. has seen a progressive increase in opioid prescriptions. During the 70s, physicians were trained to order minimal opioids for pain, and nurses were trained to give minimum dose of prescribed opioids, often less than the prescribed dose. Unless death was imminent, a patient's pain was undertreated and poorly managed. In the following decade, studies done on small groups of patients, mainly inpatient, suggested use of opioids for pain control in chronic cancer and non-cancer patients. These studies deemphasized the risk of addiction to prescription opioids. There was no long-term study of effects of opioids and no published data on use of opioids for chronic pain (Meldrum, 2016). Around the same time, World Health Organization (WHO) recommended opioids for treating cancer pain and for pediatric chronic noncancer pain (Scholten, Christensen, Olesen, & Drewes, 2019).

By the 1990's there was a rise in opioid prescriptions. Controlled substances were ordered not only to manage acute pain after surgery, pain in advanced cancers and pain in patients who were terminally ill, but also to manage intractable and chronic pain. In the same decade, pharmaceutical companies caught on to the idea of mass producing and promoting opioids. There was a widespread perception that prescription opioids were not addictive. Due to the American Pain Society's designation of pain as the fifth vital sign and recommendation to physicians to aggressively manage patient's pain, the physician practices experienced a surge in opioid prescriptions. The health insurance companies provided good coverage of patient's opioid

prescription but rather poor coverage of non-pharmacologic approaches to pain management, such as physical therapy. Lack of health insurance coverage led to more patients using opioid prescriptions to manage pain (DeWeerdt, 2019).

As the movement to manage pain better gained momentum, the sale of prescription opioids increased in the 1990s, and quadrupled between 1999 to 2010. There was an increase in non-prescription and illegal opioid use seen parallel to the prescription opioid increase (Bonnie, Schumacher, Clark, & Kesselheim, 2019). Drug companies, such as Purdue Pharma, did aggressive marketing of opioids as safe for long-term use. Due to abundant opioid prescriptions, there was an increase in scheduled substances available to the public in their homes, which resulted in misuse, drug diversion and illegal sale. An increasing number of patients became addicted to opioids and there was an increase in drug-seeking behavior. Patients changed providers, pharmacies, and sometimes their hometown to gain a prescription for opioids, either for personal use or to sell on the streets for a higher price. Those who could no longer afford or were denied a prescription, took to drug traffickers and cheap street drugs to fulfil their addiction needs. The years 2000-2014 saw an alarming 137% increase in controlled substance overdoses and a 200% increase in overdose deaths (Meldrum, 2016).

Opioid Guidelines in the United States

Mild to moderate pain can be effectively managed with non-opioid analgesics, however stronger pain medications are needed to manage severe pain. Many cancer patients live with moderate to severe pain throughout their life, either due to nature of their disease or due to long-term effects of cancer treatment. Cleary, Gelband and Wagner (2015) explain that cancer pain equally affects the rich and the poor, especially toward the end of life. So, the use of "opioids—such as codeine and morphine—are invariably needed toward the end of life" (Cleary, Gelband,

& Wagner, 2015, p. 166). Because of this, international and national guidelines and recommendations continue to vouch for a need of opioids to manage cancer and terminal pain.

The World Health Organization (WHO) recommends opioid agonists for moderate to severe cancer pain. Opioid medications such as morphine have been included in the WHO Model List of Essential Medicines for adults since 2002, and for children since 2007 (WHO, September, 2019; WHO, 2019). Additionally, to treat pediatric patients, "several other opioid agonists are included in the WHO Guidelines on the Pharmacological Treatment of Persisting Pain in Children" (Duthey & Scholten, 2013, p. 284). Effective pain and symptom control in end-of-life care can allow patients to progress through the dying process in a safe, dignified, and comfortable manner. The Centers for Disease Control and Prevention (CDC) released guidelines for prescribing opioids to treat chronic pain outside of active cancer, palliative, & end-of-life care. The CDC defines chronic pain as a condition lasting more than 3 months or past the normal healing of tissue injury. The purpose of these guidelines is to improve opioid prescription practice for safe and effective pain treatment, and to reduce harm to the patient (CDC, 2019).

Similarly, the U.S. Department of Health and Human Services (HHS) recommends and offers opioid & pain management education for medical professionals. HHS recognizes medical professional's role in safe prescription and management of opioids. When prescribing opioids, HHS recommends assessing risk to the patient, educating patients, and co-prescribing naloxone. Naloxone is an "opioid-antagonist" that is used to treat opioid overdose. It is used to "counteract life-threatening depression of the central nervous system and respiratory system" **(**Harm Reduction Coalition, n.d., para 1) so that person can begin to breathe normally. If administered on time, naloxone can temporarily reverse opioid effects and prevent overdose death (SAMHSA, 2018).

The National Hospice & Palliative Care Organization, National Association for Home Care & Hospice, and American Academy of Hospice and Palliative Medicine continue to emphasize importance of pain management in palliative and EOL patients. Additionally, these national organizations recommend and offer continued training and education to medical professionals on pain management, safe opioid prescribing, and opioid risk mitigation when prescribing opioids to patients during palliative and EOL care.

Problem Statement

The current state of the opiate epidemic has caught regulators' attention. There has been development of new federal and state-level interventions to guide opioid prescription and disposal practice. During site surveys, hospice accrediting bodies, and federal and state surveyors specifically review hospice operations' compliance with those rules. To assure safe opioid treatment to patients, and to stay compliant with federal and state regulations, hospice operators must align their policies with national and local rules. As per the WHO 2018 report, "clinical and policy guidelines should be complementary in order to increase overall access to controlled pain relief medicines" (WHO, 2018, p. 23). There are federal as well as state opioid regulations. However, state opioid regulatory changes are not standardized across all state lines. Hospice providers need a detailed review of federal and state-level opioid regulations and practice rules to develop or revise opioid prescription and disposal policies and protocols. There was no one professional society, organization, website, or hospice practice that has federal and all U.S. state's opioid regulatory data. An opioid regulation and practice rule data repository was needed to house the federal and state rules at one central location. The data was collected from literature review, professional and national organizations, and federal and state legislatures. This regulatory data repository can provide ready access to federal and state opioid rules and

regulations for a systematic review. A detailed review of this regulatory data can help develop an opioid policy for hospice clinicians. This opioid policy can further inform hospice practice protocols for standardization of care. Implementation of informed policy and protocol can assure regulatory compliance and medico-legal fortitude for a multi-state healthcare organization.

Significance of Addressing the Problem

Healthcare in the United States is complex and heavily regulated. Hospice practice is no exception. Federal and state authorities publish rules and directives that guide health industry operations and impact clinical practice. The Centers for Medicare and Medicaid, the Health Insurance Portability and Accountability Act, the United States Drug Enforcement Administration (DEA), and the U. S. Food and Drug Administration are a few of the many federal regulatory authorities impacting hospice practice. In addition, each state may have hospice rules, drug rules, and state practice acts that guide hospice operations. To develop policy and practice protocols, a multi-state hospice organization needs to review federal as well as state guidelines across the state lines. Hospice providers have to sift through this web of rules and regulations to provide safe and compliant patient care.

The nation is currently going through a major opioid epidemic. Providers across the country are trying to keep up with the changing landscape of federal and state opioid rules. Hospice providers (physicians and nurse practitioners) prescribe opioids to hospice patients and monitor patients for pain and symptom relief. A lack of a central opioid regulation repository makes it cumbersome and challenging to search through a myriad of resources to develop an informed policy. That's why developing an opioid regulatory catalog containing the most pertinent and relevant rules and statutes is the first logical step toward an informed organization-wide policy. Also, currently there's no review of opioid rules and regulations literature available for

systematic policy development. That's why a thorough review of opioid regulations and statutes is the next logical step in policy development. A qualitative analysis of opioid rule data will identify opioid guideline themes in favor of, neutral to, or not in favor of hospice practice. The themes will guide the development of hospice policies and practices for the prescribers. To comply with federal and state opioid regulatory requirements, an up-to-date policy can be a reliable source to guide development of clinical practice protocols. A lack of federal and state opioid regulations review may misinform policy development, cause noncompliance with published rules, risk regulatory authority scrutiny, and compromise patient care.

CHAPTER 2

Review of the Literature

A review of the literature for current state of opioid regulatory changes and policies to guide safe patient practices was conducted (Appendix A). A search was conducted using the Cumulative Index of Nursing and Allied Health Literature (CINAHL), PAIS Index, and Ovid Medline databases using the following keywords: end of life, palliative care, hospice, pain management, cancer pain, opioid, policy, rules, standards, recommendations, practices, prescribe, overdose, addiction, naloxone, toolkit, and repository. In addition to the keywords, three Boolean operators were used for the search: and, or, and not. The search yielded 419 scholarly articles of which 19 were reviewed. Articles supporting evidence for opioids used in end of life and cancer pain were included in the review. Literature was excluded if the article did not include opioid use in pain management.

Resources also included relevant federal, state, and local agencies and professional organizations for guidelines, such as the Centers for Disease Control and Prevention, the International Association for the Study of Pain, the National Conference of State Legislators, the National Science and Technology Council, the National Cancer Institute, the Prescription drug abuse policy system, the Substance Abuse and Mental Health Services Administration , the U.S. Department of Health and Human Services, and the World Health Organization. The literature review provided insight into the current opioid crisis in the United States, and federal and state strategies to address this opioid crisis.

Current Opioid Crisis

The beginning of the 21st century saw a rise in strategies to better manage pain in Americans, including recognizing pain as the fifth vital sign. In the year 2000, Veterans' Health

Administration established protocols throughout the system to routinely screen and assess pain in patients. The strategy was that patients were not to be denied analgesics due to fear of addiction or side effects. In 2001, the Joint Commission released pain management accreditation standards for ambulatory, inpatient as well as home care providers. The standards recognized and recommended that pain assessment and management is a patient's right. This was a paradigm shift towards accepting patient's subjective reporting of pain over the ill effects of opioids. The physicians found failing to adequately treat a patient's pain were disciplined, fined, or sanctioned. Medical boards were addressing complaints of inadequate prescribing to manage patient's pain and, in litigation against physicians undermanagement of patient's pain was considered neglect. In 2004, the Federation of State Medical Boards policy advised state medical boards that overtreatment and undertreatment of pain were both equally considered a violation of the standard of care (Garcia, 2013).

As the philosophy of pain management and perception of painkiller prescriptions shifted, the quantity of prescription opioids sold to pharmacies, hospitals, and medical clinics steadily and sharply increased between 1999 and 2010. The health insurance payors saw a cost saving in restricting reimbursement for non-pharmacologic interventions for pain management, such as physical therapy, cognitive-behavioral therapy, and complementary and alternative medicine (Tompkins, Hobelmann, & Compton, 2017). The number of pain management clinics focusing on pain treatment through opioid prescription increased and primary care practitioners prescribed opioids without education or warning patients of the risk of addiction. The increased use of prescription controlled substances led to abundant availability of opioids in the community. This in turn led to a rise in opioid misuse, abuse, diversion, nonmedical use, and overdoses. The opioid addicted nonmedical users turned up at emergency departments to fulfill their needs. The

nonmedical prescription opioid use is costing American insurers approximately $72.5 billion annually (Garcia, 2013). Those who couldn't afford a prescription painkiller took to the streets to buy cheaper versions of the opioids. This gave rise to an illicit drug market where drug-traffickers reached the American middle-class (Meldrum, 2016).

The United States is thus facing an opioid crisis caused by opioid practices from the past three decades. The opioid epidemic has equally impacted all ages, gender, and every socioeconomic group in the United States (Bonnie, Ford, & Phillips, 2017). No corner of the country is untouched by the ill effects of the opioid epidemic.

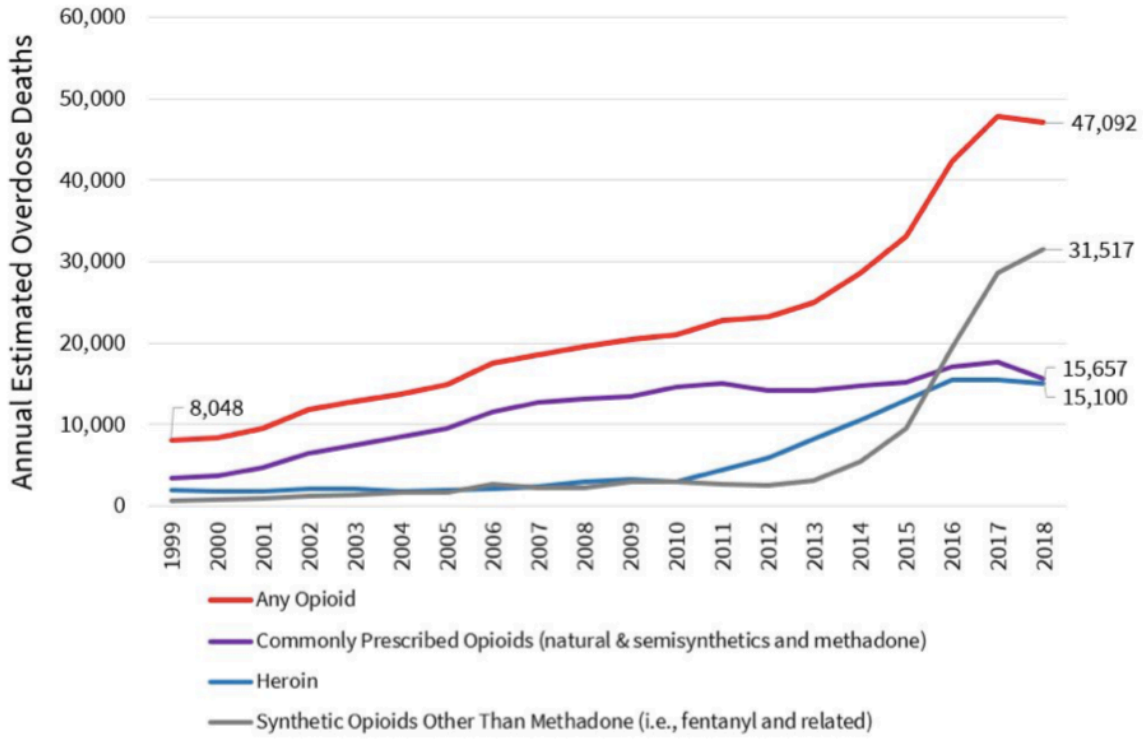

Figure 1. Drug Overdose Deaths in the U.S. Involving Opioids, 1999 to 2018. Source: National Center for Health Statistics WONDER (1999-2016) and Provisional Drug Overdose Death Counts (2017-2018), National Vital Statistics System, Mortality, National Science & Technology Council. Retrieved from https://www.whitehouse.gov/wp-content/uploads/2019/10/Health-Research-and-Development-for-Opioid-Crisis-National-Roadmap-2019.pdf December 2019.

Between 1999 and 2010, the number of opioid prescriptions sold quadrupled and prescription painkiller overdose deaths tripled. By 2018, the overdose deaths from prescription & illicit opioid use had reached 42,250, an alarming level of five times the 8,050 overdose deaths in the year 1999 (NSTC, 2018) (Figure 1). Meldrum (2016) brings attention to "an alarming increase in heroin use across the country and an epidemic of drug overdose deaths, which increased 137% between 2000 and 2014; overdoses involving prescription opioids and heroin increased 200% in that period" (p. 1366). Children born to opioid users experienced opioid withdrawal. The opioid crisis had now extended from families to communities in the United States (NSTC, 2018). In 2017, under President Trump's direction, HHS Secretary Eric D. Hargan declared the opioid crisis a public health emergency in the U.S. (HHS, 2017).

Federal Strategies to Address the Opioid Crisis

CDC recognizes that long-term opioid use in noncancer nociceptive and neuropathic pain presents a serious risk to the patient and adds the burden of managing the prescription use to the primary care practices. In 2016, the CDC released opioid guidelines for primary care providers. In the guidelines, the CDC has opioid prescribing recommendations to treat chronic pain in outpatient settings. The rationale of these guidelines is to improve primary care provider knowledge and opioid prescribing practices to safely manage patient's pain in an outpatient setting. The CDC guidelines clarify that active cancer treatment, palliative care, and end- of-life care opioid prescribing is excluded from these guidelines (Dowell, Haegerich, & Chou, 2016). The CDC released an advisory statement in April 2019 clarifying the scope of application of 2016 CDC opioid prescription guidelines. The guidelines are not intended for patients in active cancer treatment, patients experiencing acute sickle cell crises, patients experiencing post-

surgical pain, patients who already prescribed a higher dosage (≥90 MME/day) of opioids, or for use in patients on medication-assisted treatment for opioid use disorder (CDC, 2019).

On March 19, 2018, President Trump declared his plan to fight the opiate crisis with priority to "improve access to prevention, treatment, and recovery support services; target the availability and distribution of overdose-reversing drugs; strengthen public health data reporting and collection; support cutting-edge research on addiction and pain; and advance the practice of pain management" (HHS, 2017, para 7). As a result, Congress funneled more funds in the fiscal year 2019 budget to assist federal, state, and community organizations to combat the opioid crisis through opioid addiction prevention and treatment programs; overdose, reversal, and recovery policies; and research and development. This funding can expand coverage through the Affordable Care Act to assist in increasing existing addiction treatment benefits for the uninsured (Hahn, 2018). The changes in federal policy have fueled initiatives to address and drastically change current opiate treatment projects and policies for both practitioners and patients. The interventions for patient safety include Centers for Disease Control guidelines for prescribing opioids for chronic pain, Prescription drug monitoring programs (PDMPs), naloxone for opiate overdose emergencies, and expansion of medication assisted treatment (MAT) (Painter, 2017; McGinty et al., 2018).

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act or the SUPPORT for Patients and Communities Act was enacted in 2018. Despite differences among Democrats and Republicans on many policies of national interest, the SUPPORT for Patients and Communities Act received bipartisan support. Under SUPPORT for Patients and Communities Act, there are provisions to address the opioid crisis and patient safety for Medicaid, Medicare, and other health insurance enrollees, including mental

health parity for substance use disorder (SUD), safe disposal of unused medication provision for hospice providers, provisions for emergency departments, empowering pharmacists and prescribers by developing opioid prescribing and dispensing best practices. The act has provisions for grants for peer support communities of recovery and regional centers for SUD education (S. 2680, 2018).

Additionally, under the SUPPORT Act, there is a provision for expansion of existing programs to address the opioid crisis – expanding access to telehealth and federal reimbursement for SUD, incentives for prescribing opioid alternatives, and empowering the providers to use MAT for effectively treating SUD and sustaining recovery (McCullough, 2018). Successful and uniform implementation of the Mental Health Parity and Addiction Equity Act, and its alignment to evidence based federal, state, and community level opiate treatment programs depends on – collaboration and communication among stakeholders and agencies, creation and standardization of education materials and clinical tools, and state evaluation of the practices and operations of an insurer (Painter, 2017).

In the Substance Abuse and Mental Health Services Administration (SAMHSA) opioid overdose prevention toolkit, one of the strategies recommended to prevent overdose death is ensuring ready access to naloxone. Naloxone is not an addictive medication and thus has no abuse potential; it only works in the body if an opioid is present otherwise it has no effect on the body. Another benefit of naloxone is that it can be injected or administered intranasally with equal ease either by trained medical professional or by layperson.

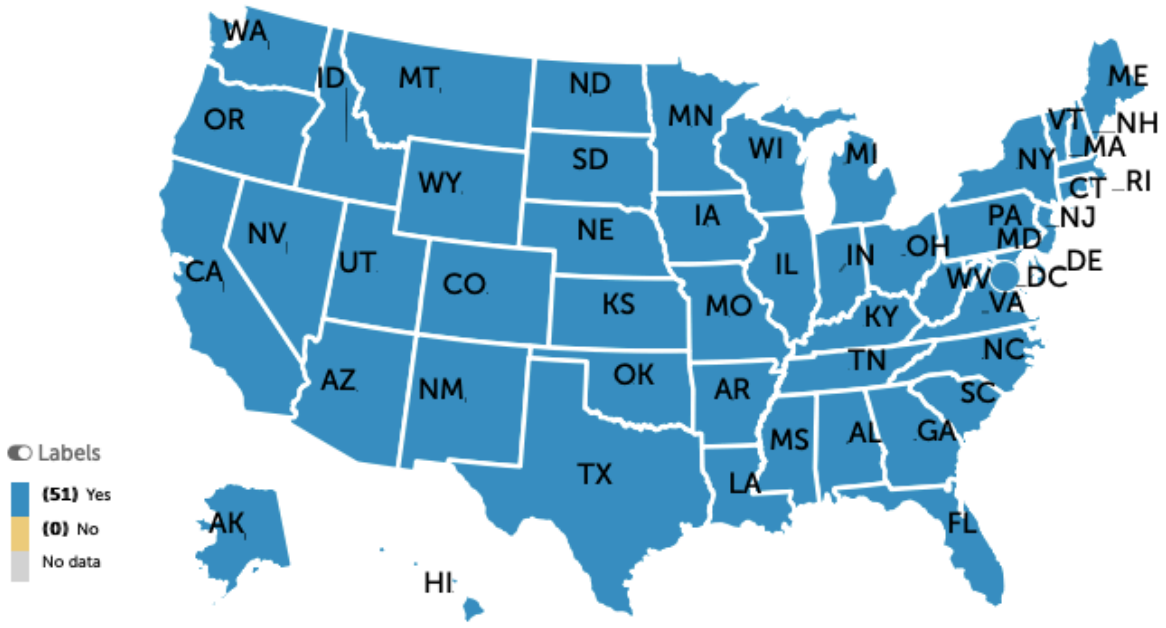

Figure 2. Does the jurisdiction have a naloxone access law? Reprinted from National institute on drug abuse' Prescription drug abuse policy system (PDAPS). Retrieved from http://pdaps.org/datasets/laws-regulating-administration-of-naloxone-1501695139 December 2019.

Ease of use makes it an ideal medication to use in a prescription opioid as well as heroin overdose **(**Harm Reduction Coalition, n.d.). Moreover, it is available at pharmacy stores at low or no cost (SAMHSA, 2018). The national naloxone initiative to reverse an opioid overdose is currently operating in all 50 states and supports the use of naloxone for opiate overdose emergencies (SAMHSA, 2017) (Figure 2).

State Strategies to Address the Opioid Crisis

State regulatory bodies are addressing the opioid overdose crisis through policy and regulatory efforts. State legislators establish regulations, and state regulatory bodies such as, the health department or the state licensing authority, implement and enforce those regulations. States are addressing opioid overdose issues, inappropriate opioid prescription issues, and safe opioid prescribing by establishing prescription drug monitoring programs (PDMPs), regulating

pain clinics, and establishing opioid dosage thresholds (Garcia, 2013). Also, states are addressing the complexity of the opioid crisis by imposing regulatory requirements in addition to enforcing federal laws (Garcia, 2013).

Prescription drug monitoring programs. PDMPs are state administered centralized electronic databases to track opioid prescriptions. The database enables prescribers and pharmacies to screen and monitor history of patient's prescription medication use. The database facilitates recognizing potential prescription medication abuse or diversion. PDMPs empower state regulatory bodies to monitor prescribers inappropriate prescribing and pharmacies inappropriate dispensing behaviors.

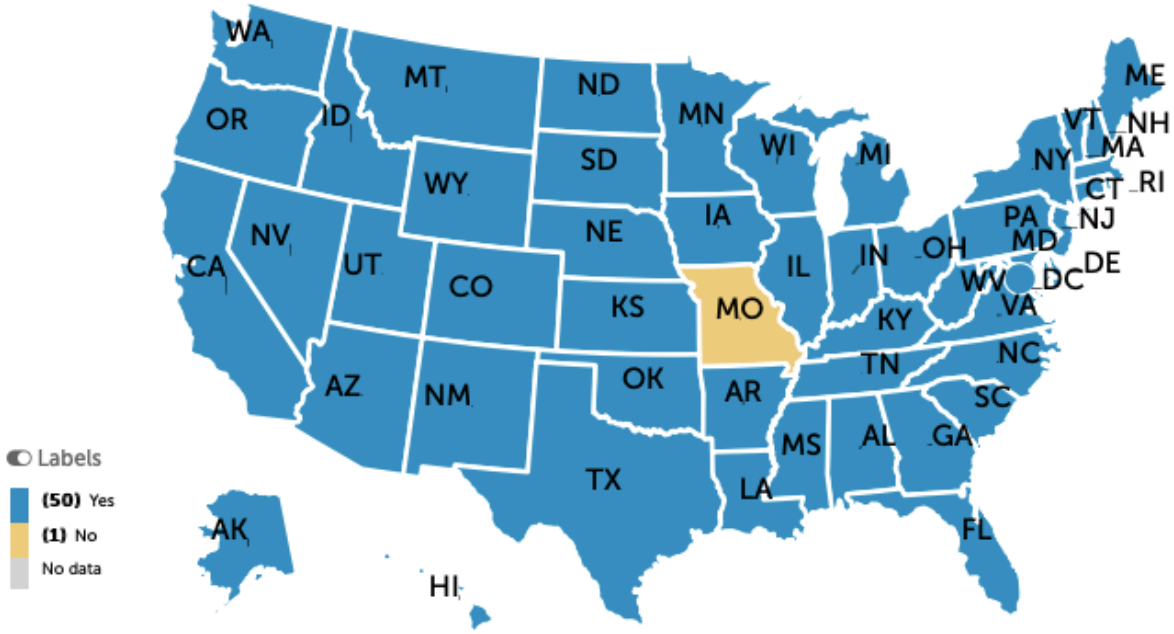

Figure 3. Does this state have legislation authorizing a PDMP? Reprinted from National institute on drug abuse' Prescription drug abuse policy system (PDAPS). Retrieved from http://pdaps.org/datasets/prescription-monitoring-program-laws-1408223428-1502818371. December 2019.

Currently, 49 states and District of Columbia have mandatory PDMP laws (Figure 3). The state of Missouri is the only state that has not been able to pass the PDMP bill through its state

senate seven years in a row (Howell, 2017; Weber, 2019). The mandatory PDMP enrollment law requires prescribers and pharmacies to enroll in to access the database. In addition, the mandatory PDMP query laws require prescribers and pharmacies to check their state's PDMPs prior to prescribing opioids. PDMP law prevents doctor shopping and rogue physician prescribing practice (Painter, 2017; McGinty et al., 2018; Garcia, 2013).

Regulating pain clinics. As shown in figure 4 below, as of May 2018, 12 states have enacted some kind of pain management clinic law (PDAPS, 2019) (Figure 4). These laws regulate the clinic's protocols, physician prescribing practices, and owner accountability.

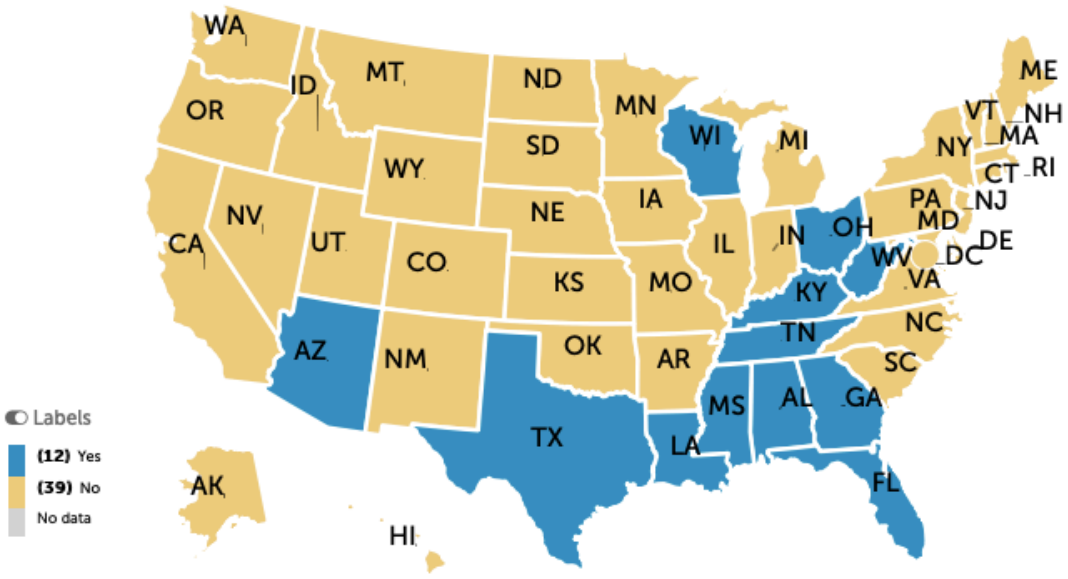

Figure 4. Is there a pain management clinic law? Reprinted from National institute on drug abuse' Prescription drug abuse policy system (PDAPS). Retrieved from http://pdaps.org/datasets/pain-management-clinic-laws December 2019.

The difference between a legitimate pain management clinic, and a "pill-mill" pain clinic is their prescription practice. The pain management clinics treat and manage patient's chronic pain and prescribe a controlled substance to the majority of their patients. These clinics have a licensed physician trained in safe pain management practices providing oversight to the program.

The other licensed providers at these clinics are also trained in safe pain management practices, including recognizing signs of addiction & diversion. These clinics are usually affiliated with a hospital or a larger health care system. The "pill-mill" pain clinics, on the other hand, are mostly run by private owners who are not medically trained. The purpose of these clinics is maximizing patient volume to maximize profit. These clinics do not institute legitimate pain management practice, operate cash-only, refer all their patients to one diagnostic facility, and prescribe identical opioid prescription to all patients. (Garcia, 2013).

Establishing Dosage Thresholds. Since the release of CDC opioid guidelines in 2016, states have been considering opioid policy revisions. As of October 2018, >30 states have enacted laws setting limits on opioid prescriptions. The CDC guidelines for prescribing opioids recommend cautious opioid prescription dosages for safe and more effective pain treatment. Prescribing lowest effective dosage and titrating up or tapering down based on individual benefits helps keep a close watch on the patient. The CDC recommendation is to weigh in individual risk when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and to avoid increasing dosage to ≥90 MME/day. However, the guidelines recommend that the clinician should carefully consider rationale & effects if dosage needs to be titrated to ≥90 MME/day (CDC, 2019).

To control the quantity of opioids prescribed and dispensed in the community, states have enacted laws restricting opioid prescription to a certain number of days of supply (Figure 5). These restrictions are mostly for first-time opioid prescriptions and allowed number of days of supply ranges from 3 days to 14 days. Some states specify that these restrictions are for managing acute pain, and provide exceptions for chronic, cancer, palliative, and hospice patients.

Many state laws have provisions to allow for exceptions for patients who are receiving medication-assisted treatment (MAT) for substance-use disorder (SUD) (NCSL, 2019).

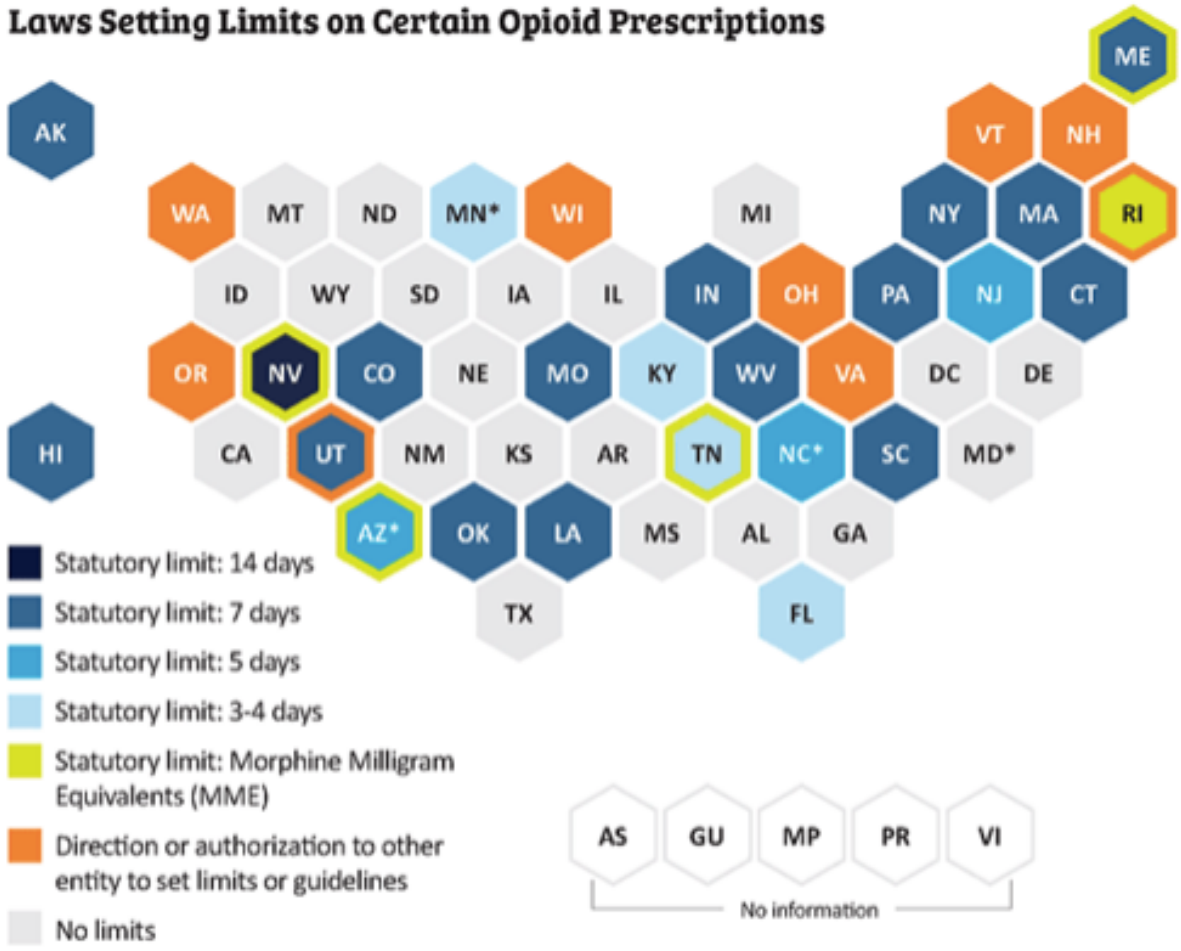

Figure 5. Laws setting limits on certain opioid prescriptions. Reprinted from National conference on state legislatures (NCSL). Retrieved from http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx December 2019.

In addition to setting initial opioid prescription limits for adult patients, Alaska, Connecticut, Indiana, Louisiana, Massachusetts, Nebraska, Pennsylvania and West Virginia have also set opioid prescription limits for minors. Additionally, these state regulations require opioid education, including discussing opioid risks and side effects, with minor patients and their adult

caregivers. In contrast, states such as New Hampshire, Ohio, Oregon, Vermont, Virginia, Washington and Wisconsin have not enacted the opioid prescription limit statute. They direct other state regulatory authorities, such as the health department or board of medicine to institute opioid prescribing limits (NCSL, 2019).

"Overdose Good Samaritan" immunity laws related to naloxone use protect drug users who call for emergency assistance in the event of a drug overdose and may seek addiction recovery treatment after naloxone administration. Access to naloxone for overdose reversal is dependent on state policies which are not aligned across all states, and not all of the states have passed overdose Good Samaritan Law (PDAPS, 2019; SAMHSA, 2017) (Figure 6).

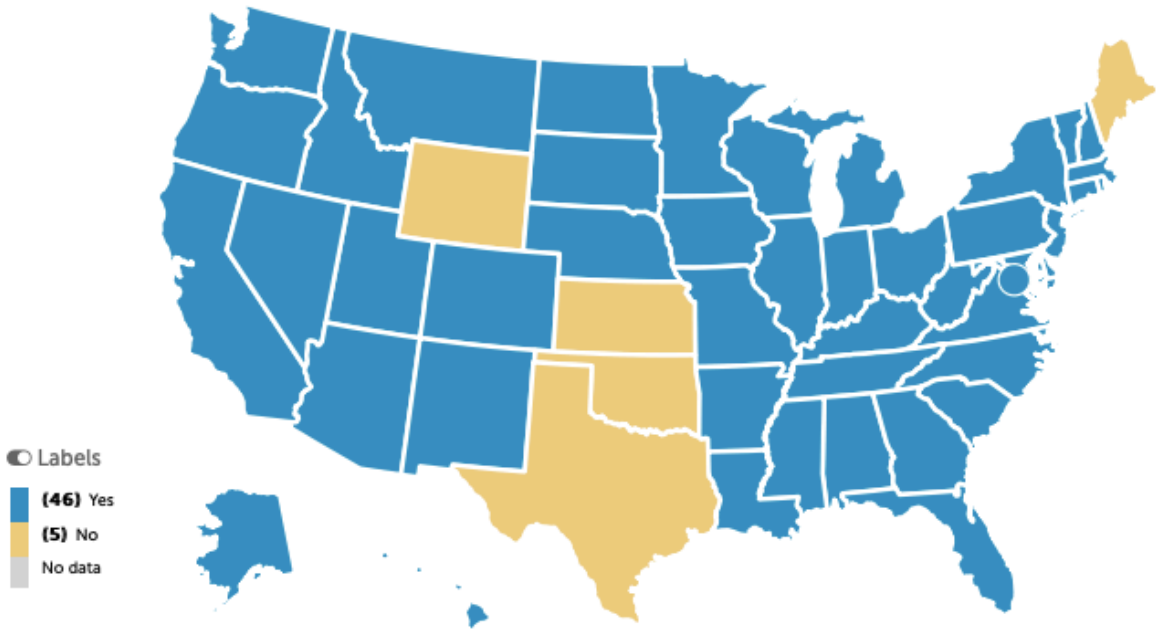

Figure 6. Does the jurisdiction have a drug overdose Good Samaritan Law? Reprinted from National institute on drug abuse' Prescription drug abuse policy system (PDAPS). Retrieved from http://pdaps.org/datasets/good-samaritan-overdose-laws-1501695153 December 2019.

While Overdose Good Samaritan immunity laws vary by state, they all consider either decriminalizing or mitigating actions for possession and use of drugs (SAMHSA, 2017). Enactment of this law is a step towards lifting the stigma and changing the thought process that opioid misuse is a choice. Also, separating the drug user laws from drug seller laws is appreciated by lawmakers and the public. Spotlight on the opioid misuse issues has changed policymakers' perceptions and fostered an understanding that opioid misuse is a medical condition in need of treatment (Johnson, 2018; Saunders, Jarlenski, Levy, & Kozhimannil, 2018).

Along with instituting new opioid policies, states have revised and remodeled existing laws and policies (Parker, Strunk, & Fiellin, 2018). On a community level, syringe exchange programs are one such comprehensive strategy to address the health of people with SUD. Currently, 41 states have syringe exchange programs. These programs promote prevention of drug-related transmission of infections by providing access to free sterile syringes and needles, and safe disposal of used syringes and needles. Syringe exchange programs are providing much needed resources for the community by targeting high-risk areas (Painter, 2017). Reforms in opioid prescribing practices will help prevent substance abuse, diversion and overdose, while ensuring legitimate access to pain management. Opioid prescribing cap laws limit the number of days' supply and/or dose of prescribed opioids. Pill mill laws strictly regulate pain management clinics to prevent rogue clinics (pill mills) from issuing opioid prescriptions without medical indication or necessity (Mcginty et al., 2018).

Literature Gap

Since the 2016 release of CDC opioid prescription guidelines, there has been a flood of opioid related laws and policies being enacted at the federal as well as the state level. These

opioid prescription laws are not uniform across all the states, and not all states have an opioid prescription law. Most federal and state opioid regulations have provisions to exempt cancer, palliative care and hospice patients, but not all. While bipartisan efforts to curb the opioid epidemic continue at all levels, disparity remains among states regarding opioid policies (Painter, 2017). Fear surrounding inappropriate use of opioids and an increase in opioid related regulations have caused unintended consequences for the hospice patients (Fehlberg, Broyles, Wu, & Halpern, 2018). Due to fear of being scrutinized by the state regulatory authority or a state professional board, physicians are prescribing minimum dosage of opioids. By prescribing a minimum dosage, the prescriber doesn't have to deal with opioid risk mitigation required when prescribing higher dosage of opioids to the patient. Even when the controlled substance is prescribed to a hospice patient, pharmacies in many states are restricting quantity of medication dispensed to the minimum number of days allowed by the state law. Hospice patients need opioids for pain relief from advanced illness and hospice practitioners need to be knowledgeable of opioid regulations to abide by the law and to provide care without delay. Hospices need to review opioid regulations and create policies for opioid use in inpatient and home-hospice setting. A review of current opioid regulations and development of opioid prescription, use, and disposal policies and practices will provide clarity to hospice and palliative care practitioners engaged in care of EOL advanced cancer and non-cancer patients. These policies will guide the hospice clinicians of their role and responsibility while caring for patients who are prescribed opioids at EOL. This exercise will also advise hospice & palliative care practices to comply with federal & state opioid regulations.

Theoretical Framework

The Knowledge-to-Action (KTA) Process Framework (Figure 7) is a theoretical framework in evidence-based implementation of knowledge into action. Graham et al. (2006) proposed the KTA process conceptual framework to encourage use of research knowledge by a variety of stakeholders in healthcare, from bedside clinician to boardroom executive. The KTA process has two components: (1) knowledge creation and (2) action. Each component consists of several phases on which the model continues to build. KTA is a dynamic and complex process, where

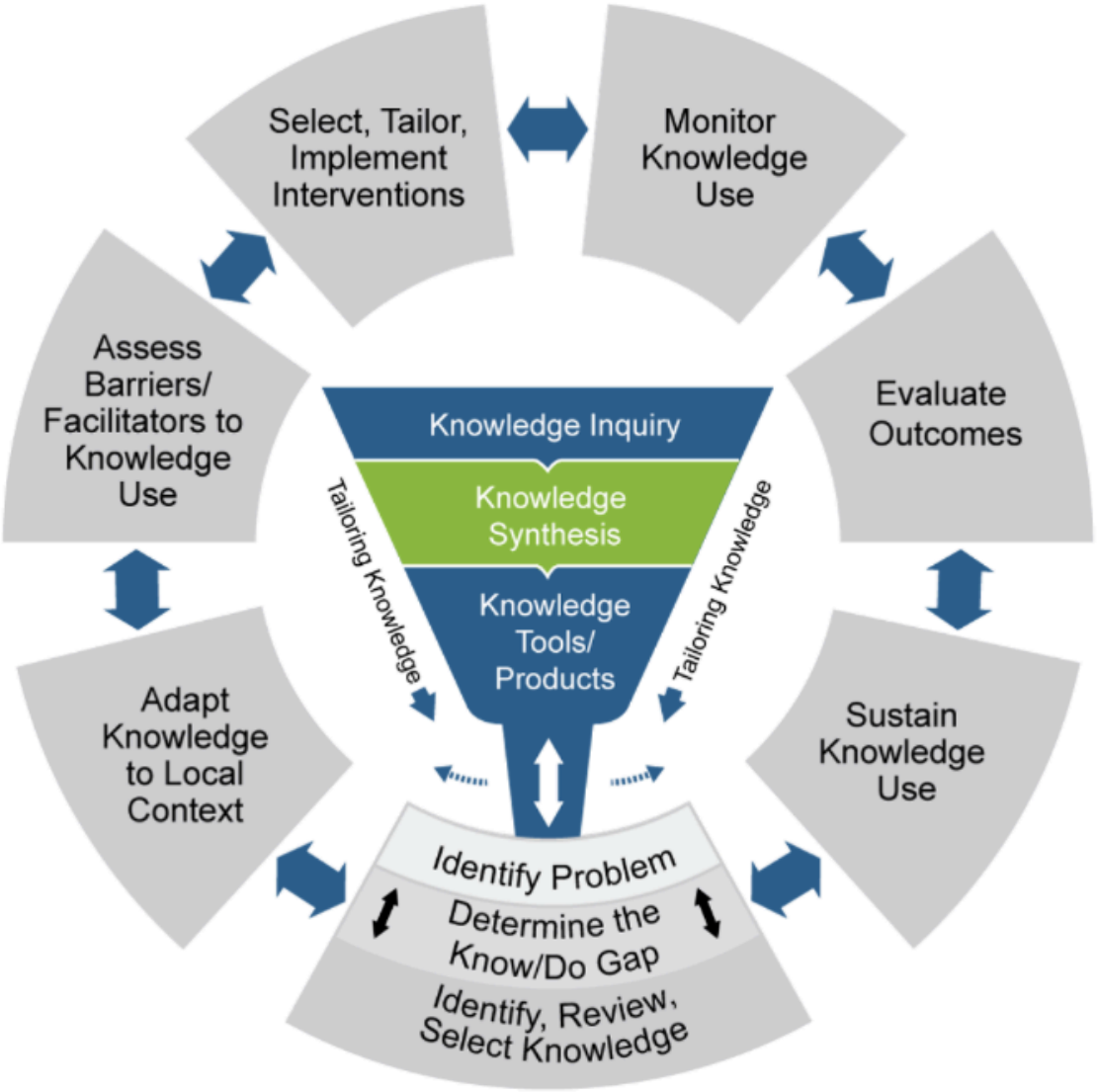

Figure 7. The Knowledge-to-Action Framework (KTA Framework). Reprinted from The

Knowledge-to-Action Framework. Retrieved from https://medium.com/knowledgenudge/kt-101-the-knowledge-to-action-framework-7fbe399723e8 October 2019

the framework knowledge creation process can be applied into action for long-term sustainability. The two components have several sequential or simultaneous phases. These phases are contained in a cyclic model to allow for a constant feedback loop.

The knowledge creation component consists of knowledge inquiry, knowledge synthesis, and knowledge tools to tailor into creating knowledge for action. It is shaped as an inverted funnel to gather several pieces of knowledge and filter the most applicable and refined knowledge toward the action component. The knowledge built is moved into the next component, action. Action has a series of phases that include adapting the knowledge, implementing in the setting of choice, monitoring knowledge use and evaluating outcomes. Barriers and facilitators to the implementation process are addressed within the action component as well. Evaluating outcomes of the process during an action component helps determine the impact of the knowledge gained on practitioner practices, patient care outcomes, and the healthcare system. Graham et al. (2006) recommend creating a knowledge sustainability plan that can withstand system changes.

Applicability:

The KTA Process Framework aligns with the scope and purpose of this project, which is to synthesize accumulated opioid laws and regulation knowledge into actionable system-level policy for hospice practice and evaluate consistent use of the policy by hospice care practitioners (Figure 8). The cyclic process of the KTA framework places creators and users within a system which is dynamic as well as adaptive. The policies created as a result of opioid regulation synthesis will be adopted for use by hospice physicians, nurse practitioners, and nurses. The policy will inform clinical practice protocol development. As the opioid regulations change, the

policy and protocols will be modified and re-adopted. The policy built will be relevant, applicable, and intuitive for hospice practitioners' daily use. Potential barriers and facilitators to policy implementation and adoption need to be considered before implementing the policy. To help facilitate systemwide implementation, effective adoption, and continued compliance with the policy, change champions need to be identified. The desired outcome of this project is system-wide successful policy implementation and adoption.

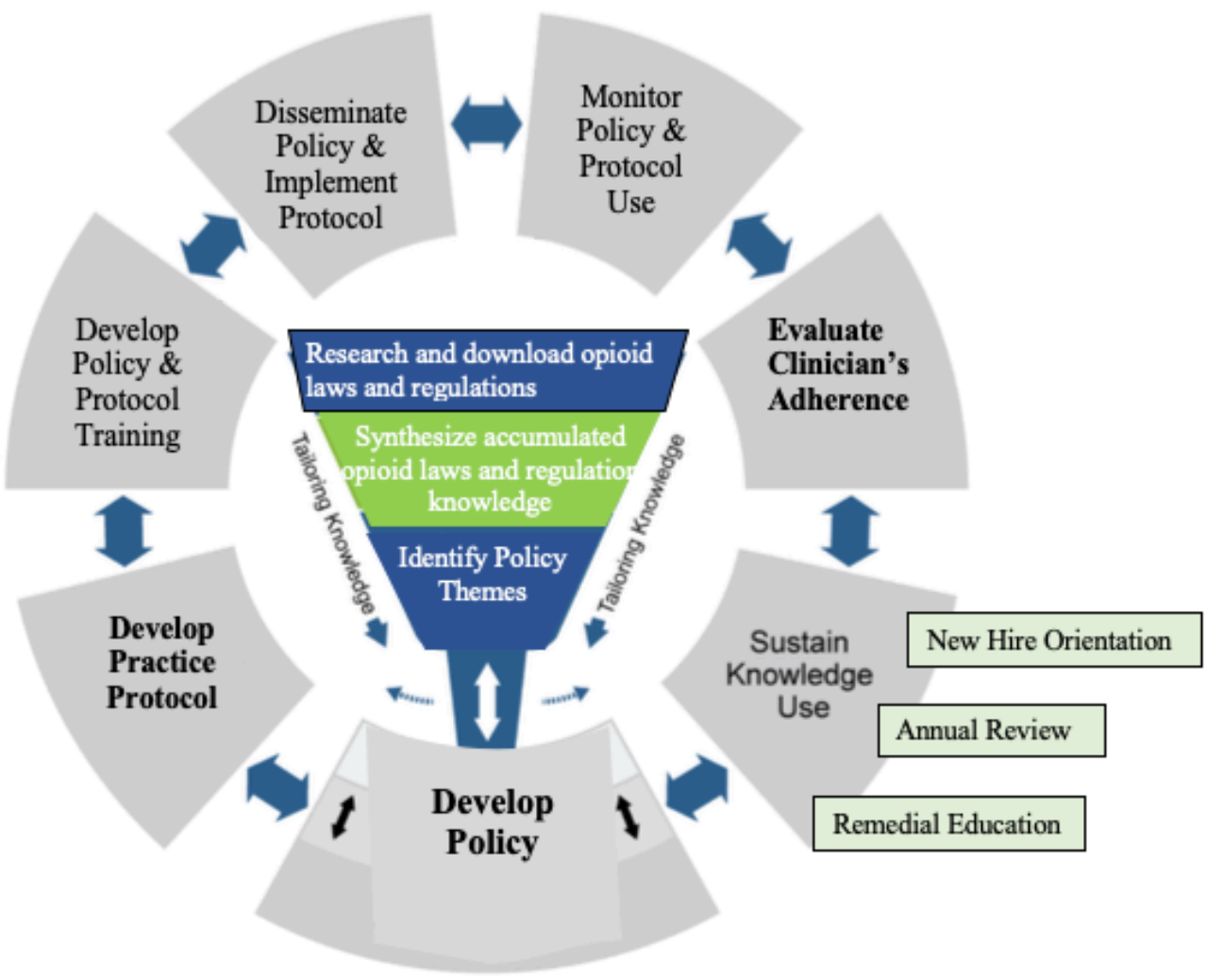

Figure 8. The KTA Framework Applicability.

Organizational Description & Analysis

Amedisys, Inc. is a for-profit healthcare at home company delivering personalized home health, hospice and personal care, with the corporate office located in Baton Rouge, Louisiana, and the executive office located in Nashville, Tennessee. Amedisys' mission is to honor those we serve with compassionate home health, hospice, and personal care services that apply the highest quality clinical practices toward allowing our patients to maintain a sense of independence, quality of life and dignity (About Amedisys, 2019). Amedisys provides in-home skilled nursing, physical therapy, occupational therapy, speech language pathology, medical social work, home aides, respiratory therapist, music therapist, life enhancement specialist, massage therapist and hospice and bereavement services. Amedisys employs approximately 16,000 individuals at more than 500 locations in more than 40 states, for providing home health, hospice and personal care services.

Amedisys Inc. (Nasdaq: AMED) recently became the third-largest hospice provider in the United States. Acquiring Compassionate Care Hospice in the year 2019 propelled Amedisys companywide into the new markets of Michigan, South Dakota, Minnesota and Nebraska, while also expanding its presence in Texas. Also, this acquisition allows Amedisys to offer a full continuum of care in Florida. In addition, the company acquired RoseRock Healthcare in April 2019, Asana Hospice in January 2020, and Aseracare Hospice in June 2020. Amedisys' post-acquisition hospice operations include 190 care centers in 35 states with an average daily census of about 12,000 patients. The idea is that by better managing beneficiary populations as they age in place and reach the end of life, these integrated providers can help keep costs down and quality high (Holly, 2018).

Since Amedisys operates multi-site hospice practice in 35 states, a review of federal and each state's opioid rules corresponding to hospice practice was needed for Amedisys' global medication management policy. This DNP project developed an opioid rule database, cross-referencing federal and state opioid rules and corresponding hospice guidelines. Amedisys' clinical services, operations, legal, and quality departments collaborated for this project. A consult with external counsel was sought as needed. The project is timely and relevant to the organization's growing multi-state operations and the aims of the project are aligned with the needs of the organization.

CHAPTER 3

Methods

The goal of this project was to develop opioid use policy specifically for a multi-state hospice practice and ensure Amedisys hospice care centers within 35 states adhere to the federal, state, and local opioid regulations. This was accomplished by downloading federal, state, and local opioid regulations and creating a repository. The downloaded regulations were appraised to create policy themes including opioid prescription, opioid use, opioid disposal, and opioid education. The regulations under those major policy themes were synthesized to create an opioid policy for hospice practice. This policy was implemented system-wide, and an evaluation of clinician's successful adherence to the policy was conducted.

Goal: Review, synthesize and reconcile federal, state, and local opioid regulations and create a system for a sustainable data base in order to develop and maintain opioid policies for implementation in care centers across 35 states to ensure ongoing compliance with opioid laws by a multistate provider.

Aim 1: Create a repository of federal, state, and local opioid regulations.

The assistant vice president of clinical regulatory (AVP Clinical Regulatory) was the project lead who was responsible for analyzing the opioid regulations and develop the opioid policy along with providing project oversight. The policy manager, who reports to AVP Clinical Regulatory, downloaded the federal, state, and local opioid regulations. The opioid regulations were searched using Google Chrome search engine with the following keywords - "opioid regulations", "opioid laws", "opioid statutes", and "opioid guidelines". Additionally, state health departments, state or local drug enforcement agencies, and federal Drug Enforcement Agency

were searched for opioid regulations. The downloaded opioid regulations were deposited in a Microsoft Office 365 SharePoint spreadsheet on the company's intranet. The purpose of using this software tool was to provide open access for employees for ease of collaboration on the project. SharePoint software has the capability to alert the document owner every time an update is made. The project lead accessed the SharePoint repository at a minimum once a week to review newly added information, and extract opioid regulations related to opioid prescription, required education for patients who are prescribed opioids, and medication disposal.

Evaluation/Analytic Plan: The policy manager was responsible for downloading the opioid regulations several times a week. During weekly review, AVP Clinical Regulatory ensured that new and/or updated opioid regulatory information has been added to the SharePoint repository. The weekly review began after this DNP project proposal was approved by the Yale school of nursing committee in Summer 2020.

Aim 2: Appraise and synthesize opioid regulations to develop a hospice practice specific opioid policy.

The KTA Process Framework was utilized that aligned well with the scope and purpose of this project. Under the framework, opioid laws and regulations were synthesized. The gathered knowledge was transferred into actionable system-level policy for hospice practice. After extracting the opioid regulations related to opioid prescription, required education for patients who are prescribed opioids, and medication disposal for each state, the AVP Clinical Regulatory conducted a comparative analysis of federal, state, and local regulations. The purpose of this comparison was to identify similarities and differences among federal, state, and local regulations. From the information extracted, the AVP Clinical Regulatory developed a draft Opioid Management policy. An umbrella policy was developed for all those states among which

there are no differences in opioid regulations (Appendix B). State specific opioid policy was created for the states with variabilities in opioid regulations that cannot be reconciled with the umbrella opioid policy due to different or additional mandates. The draft policies were sent for review and comments to the key stakeholders in the interdisciplinary opioid project team. The interdisciplinary opioid project team consisted of the hospice medical director, assistant vice president of clinical regulatory, policy manager, internal counsel, operations manager, & clinical manager. The review and comments were sought from the hospice medical director, internal counsel, & clinical manager. Internal counsel provided guidance if an external counsel review was needed. Once a month, the interdisciplinary opioid project team meeting met via phone conference call. The purpose of this meeting was to address concerns, seek feedback, and finalize policy. The recommendations from "Policy and Procedure Development Guidelines" (Irving, 2014, para. 10) are listed under Appendix C and were used to develop the policy. The policy was finalized by July 2020, and sent to hospice policy committee meeting for approval for circulation. The hospice policy committee is a standing committee that meets monthly to approve or reject requests for new policies, updated policies, and archiving policies.

Evaluation/Analytic Plan: Project lead accessed the SharePoint repository once a week to review opioid regulations, and appraise them to create policy themes. The interdisciplinary core team met once a month to assess the progress of & provide recommendations for opioid policy content and theme development. These meetings were held monthly until August 2020, then quarterly thereafter. The policy manager was responsible for sending timely meeting invites and meeting minutes following the meeting. The stakeholders, consisting of senior operations executives, were appraised monthly of the policy development.

Aim 3: Implement the policy system-wide.

After policy committee approval in July 2020, the policy manager scheduled meetings with a second team, the interdisciplinary implementation team. At this meeting, AVP Clinical Regulatory shared the policy's operational & documentation requirements with the interdisciplinary implementation team. The interdisciplinary implementation team was responsible for implementing the finalized policy system-wide, and consist of an operations manager, a clinical manager, an education manager, & EMR clinical analyst.

The opioid policy requirements were to be embedded into operational processes and electronic medical record (EMR) documentation software before system-wide policy implementation & education can occur. Under AVP Clinical Regulatory oversight, the EMR clinical analyst designed the policy updates to be embedded into the EMR software by first week of August 2020. The opioid documentation in EMR software was designed for convenience of data extraction to evaluate physicians, nurse practitioners, and nurses' compliance with the policy. The major EMR documentation categories listed were type of opioid prescription (long or short acting), clinician communication with patient, non- pharmacological & alternative options, patient education, opioid reconciliation, and opioid disposal. Appendix D contains a template of the EMR documentation categories. The EMR clinical analyst was responsible for updating the EMR operations manual including the policy and documentation updates.

Under AVP Clinical Regulatory oversight, the education manager designed policy education to be disseminated to physicians, nurse practitioners, nurses, nurse managers, and care center directors. This policy education included policy updates and EMR documentation specifications. Prior to system-wide policy implementation, the AVP Clinical Regulatory pre-informed affected personnel of the upcoming new policy. The mandatory Web-Ex policy education followed by an

e-mail policy update blast was used for policy dissemination, in addition to clinical newsletter, an online learning management system (self-education session), & onsite education sessions by the care center director during a weekly staff meeting (Appendix E). The attendees had the option to send their questions to a group email address at ~clinical.regulatory@Amedisys.com. This email is delivered to the policy manager and AVP Clinical Regulatory.

The final Opioid Management policy was planned for system-wide implementation in the third and fourth quarters of 2020. The system-wide dissemination & implementation was planned for a 17 week period in three waves, at the 6 weeks, 7 weeks, and 4 weeks mark.

Evaluation/Analytic Plan: An attendance report was extracted from the web-ex and learning management system, and the care center director was responsible for keeping attendance for the on-site policy education sessions. The operations manager reported for attendance compliance update to the core team after each mandatory Web-Ex policy education session. The plan was to provide a one on one education by the care center administrator for clinicians who were not able to attend the Web-Ex policy education. However, due to COVID-19 restrictions, those clinicians were assigned a self-learning course via online learning platform. The care center administrator was responsible for keeping attendance for the mandatory Web-Ex policy education sessions.

Aim 4: Develop a process to evaluate clinician's adherence to the opioid policy.

To hardwire the new expectations, clinicians were encouraged and recognized for opioid policy/protocol compliance. On the internal Yammer page, at standup morning meetings, or during interdisciplinary meetings, a shout out was posted for clinician and/or a care center staying compliant with opioid policy/protocol. Clinical leaders were encouraged to seek feedback from clinicians at point of care about what's working and what's not, such as, ease of

policy/protocol use, any hinderance, any feedback for protocol workflow improvement. Additionally, the plan was for change champions (peer) and supervisors to seek feedback during ride-along or competency check or staff luncheons, however due to COVID-19 restrictions, all feedback was sought via phone.

Beginning September 2020, a weekly EMR report, for each care center, was produced & reviewed by policy manager to assess compliance with policy implementation. The results were shared with core team. The purpose of this report review was to assess percentage of clinician compliance with the EMR documentation.

Evaluation/Analytic Plan: The goal was to achieve a 100% clinician compliance with state and federal regulations. For the care centers falling behind the goal, the plan was to put them on a two-part performance improvement plan. Part one was a root cause analysis (RCA) of non-compliance to determine if it's due to a system issue, a lack of understanding, or clinician negligence. Based on the results of RCA, re-education of clinicians was to be conducted.

Pre- and post-policy implementation, a comparison review of opioid-related events was conducted. The opioid-related events include prescriber failure to follow opioid prescription protocol, clinician failure to follow opioid-related patient education policy, clinician failure to follow opioid disposal protocol, and clinician failure to follow opioid medication reconciliation during every home visit to the patient. A baseline was established using opioid-related events during the calendar year 2019-2020. A robust goal was set of at least a 50% reduction in opioid-related events at the end of first 2 weeks of training, at least 75% reduction after next 2 weeks of training, and sustain at least 85% reduction after the next 4 weeks of training.

Timeline

A visualization of the detailed project timeline for the actualization of this DNP project can be found in Appendix F. Zoom, phone, or in-person meetings with DNP project advisor, Dr. Marianne Davies began in October 2018, with discussions about project topic selection, and continued with DNP project advisor, Professor Mary Ann Camilleri. The project proposal was submitted in December 2019. To seek project proposal approval, a defense presentation was scheduled in Summer of 2020 in front of the proposal approval committee of Yale School of Nursing. The review of opioid regulations to draft the opioid policy began in Summer 2020.

A policy manager was hired in April 2019 to manage opioid regulation information downloads and create the Sharepoint regulations repository. There was a total of two separate teams working under this project - the Interdisciplinary Project team and Interdisciplinary Project Implementation team. Both teams were created in Spring of 2020. The opioid policy was created by mid-July 2020. Following policy creation, the implementation team began planning for policy education, disseminations, & evaluation. The education and EMR documentation template build was completed by end of July 2020. The policy implementation, including education & dissemination of information was completed by end of Nov 2020. Attendance to policy education sessions was tracked throughout the policy implementation phase. Beginning September 2020, data from the EMR documentation compliance report was analyzed for outcome evaluation. The proposed completion date of the project was December 2020. The proposed date to have a manuscript submitted to a peer-reviewed journal or an abstract submitted to a professional conference was by January 31, 2021. The abstract has been accepted for 46th Biennial Convention (6-10 November 2021) of Sigma Theta Tau International Honor Society of Nursing (Sigma).

Leadership Immersion

Nursing education at the Doctorate of Nursing Practice level prepares the advanced practice nurse (APN) to integrate evidence into practice and shape local and global views of nursing. This DNP project allowed me to achieve my goals of working as a healthcare policy leader in the hospice and palliative care setting, becoming involved in policy analysis, policy decisions, and contributing to safe patient practices. Under the mentorship of end of life care and cancer experts, and legal and risk management experts, I implemented the project, analyzed the results, and made recommendations for practice and, if appropriate, future research.

The leadership immersion for this DNP project began in July 2020 and continued on to Spring of 2021. The sponsor of this project was VP Clinical Risk. The hospice & palliative care expert corroborating in the project was executive medical director and SVP Clinical Operations, and legal expert corroborating in the project was VP Legal. The goals of leadership immersion were engagement, collaboration, education, implementation and compliance. The interdisciplinary project teams' monthly meetings and ongoing email communications enabled engagement with the organization's clinical operations and education leaders. The interdisciplinary project team meetings held to review opioid regulations for opioid policy draft helped facilitate building knowledge through subject-matter expert feedback and understanding policy impact on clinical operations and practice. Collaboration with the project implementation team facilitated planning for system-wide policy dissemination and evaluating compliance thereafter. The implementation team members included health information technology, training, and clinical operations experts. A systematic dissemination and evaluation plan built with this implementation team's help provided consistent policy messages to the clinicians.

Chapter 4

Results

By end of November 2020, 100% of the hospice nurses, nurse practitioners and physicians received education on umbrella opioid medication policy, and state specific guidance. The system-wide dissemination & implementation was completed over a 4 week period in three waves (Figures 9 & 10). At the end of 1st 2 weeks of policy implementation, 11 states in northeast region had implementation completed. Likewise, at the end of next week, 15 additional states in south, Midwest & southeast, and at the end of final week, 9 additional states in south & west region had implementation completed. Due to social distancing restrictions uring COVID-19 public health emergency, all policy education was provided remotely via Web-Ex or online learning management platform.

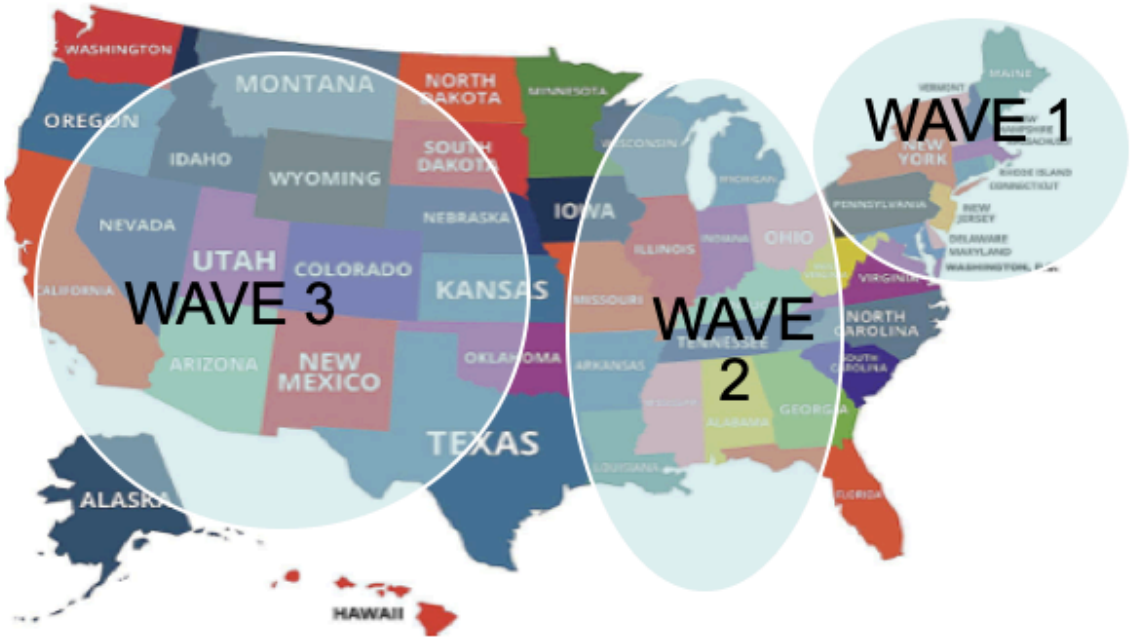

Figure 9: Regions covered under policy dissemination waves schedule

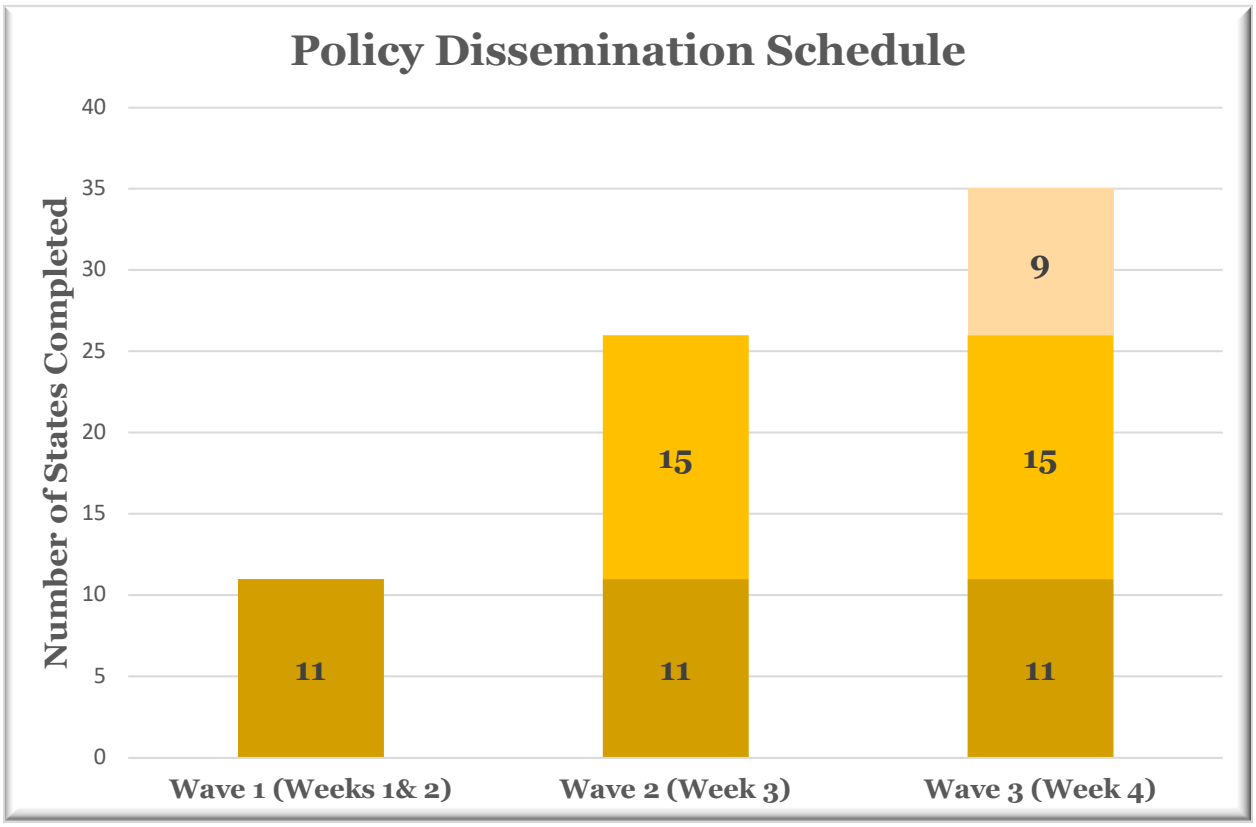

Figure 10: States completed by Wave schedule

Beginning December 1, 2020, the clinician compliance with opioid policy was monitored at the end of every week. By end of first week of December 2020, through their documentation in EMR, 100% of the clinicians in 28.5% (10 states) of all 35 states demonstrated 100% compliance with state and federal regulations (Figure 11). Sharing this result via internal Yammer page and highlighting states that had achieved compliance created a cadence of demonstrated compliance in another 22 states. By the end of third week of December 2020, 100% of the clinicians in 91% (32 states) of all 35 states demonstrated 100% compliance with state and federal regulations. These 32 states continued to maintain compliance with the umbrella opioid medication policy, and state specific guidance for the rest of December 2020.

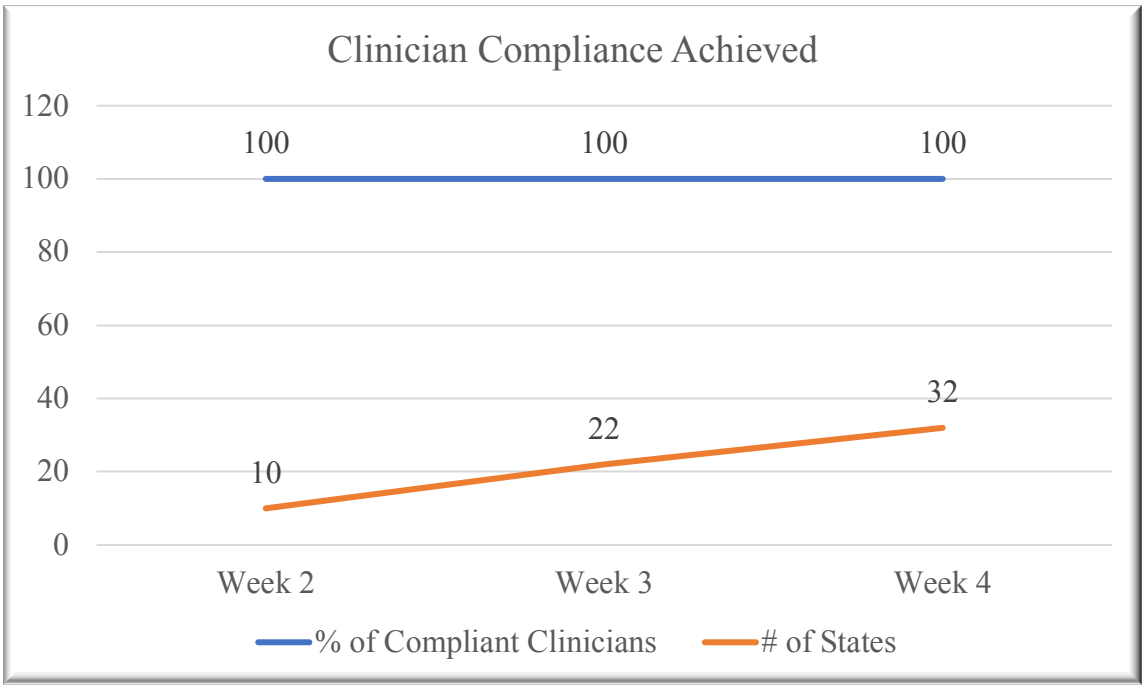

Figure 11: Clinician compliance in 4 weeks

Only 40% clinicians in remaining 3 states achieved compliance by first week of January 2021. A root cause analysis was conducted to figure out the reason for non-compliance. A user complacency to adopt documentation practices as dictated by the policy and a lack of supervision by the immediate supervisor were found to be the root cause of non-compliance with the policy. A re-education was provided to enforce policy compliance.

Pre- and post-policy implementation, a comparison review of opioid-related events was conducted. In each of the opioid-related events category, at least 50% reduction was seen. In opioid disposal category 66.66% and in medication reconciliation category 55.55% reduction was seen (Table 1).

Type of Opioid-Related Events	# Pre-Policy Implementation (Baseline) (12/2019-1/2020)	# Post-Policy Implementation (12/2020-1/2021)
Prescriber failure to follow opioid prescription protocol	2	0
Clinician failure to follow opioid-related patient education policy	6	3
Clinician failure to follow opioid disposal protocol	6	2
Clinician failure to follow opioid medication reconciliation during every home visit to the patient	18	8

Table 1: A comparison review of opioid-related events

Discussion

This project was conducted at meso and macro levels in a multi-state multilevel organization. Since the implementation of opioid policy was at a multi-state, multi-site organization, it was important to take into account barriers and facilitators to the success of the implementation. Barriers to policy implementation and adoption were activation of an emergency preparedness plan causing operational disruption, a competing regulatory requirement, and a technology breakdown. Due to COVID-19 public health emergency (PHE), the organizational resources

were diverted causing a delay of 6 months from the original timeline. In September 2020, a new hospice regulation about election of hospice benefit addendum was rolled out to be compliant with Medicare mandate. This competing regulatory requirement caused significant delay in opioid policy dissemination. The timeline was postponed to November 2020, and length of time available to complete policy dissemination was shortened to one third of the original timeframe of 17 weeks.

On the other hand, identifying change champions within the organization favorably enabled and facilitated systemwide implementation, and effective adoption, and continued compliance with the policy. The supervisors engaged in enforcing the policy guidance conducted continued monitoring of clinician documentation in EMR, and provided real time correction. Although the preparation was done to provide policy education via multiple modes, due to COVID19 PHE social distance restrictions, in-person sessions were cancelled. All policy education sessions were moved to broadcast style intranet platform or pre-recorded modules on company's learning management system. The education and operations teams were willing and quick to adapt to mode of delivery and timeline changes.

A robust goal was set of at least a 50% reduction in opioid-related events at the end of first 2 weeks of training, at least 75% reduction after next 2 weeks of training, and sustain at least 85% reduction after the next 4 weeks of training. A reduction of >50% was seen but couldn't achieve 75% reduction goal in the observed timeframe. A longer length of observation period is needed to see sustained compliance with opioid policy and sustained reduction in opioid-related events.

Implications

"Large healthcare institutions may be the most complex in human history, and even small healthcare organizations are barely manageable." ~Peter Drucker

Increasingly, the care of advanced illness patients, palliative or hospice care, is being moved to ambulatory settings. It is imperative that Quality and Safety initiatives are in place in the ambulatory setting, in the same respect as those in place in acute care settings. It also imperative that nursing healthcare policy leaders be prepared in policy analysis, change processes, business, etc. to assure safe patient care. The implications of this DNP project are two-fold. First, this project seeks is to assist hospice practices to meet regulatory compliance by making available the most current legal and regulatory information to guide institutional policy and daily patient care practices. In doing so, the risks associated with using outdated information, including noncompliance with legal and regulatory requirements, will be mitigated. Second is to promote patient safety by system-wide implementation of the policy. This will enable uniform practitioner practice and reduce harm to the patient associated with variable practices within a specific site location or region. If the company fails to comply with applicable laws and regulations, it could be subjected to liabilities, including criminal penalties, civil penalties (including the loss of our licenses to operate one or more of our businesses) and exclusion of a facility from participation in the Medicare, Medicaid, and other federal and state health care programs. If any of our facilities were to lose its accreditation or otherwise lose its certification under the Medicare and Medicaid programs, the facility is at risk for loss of reimbursement from the Medicare and Medicaid programs and other payors (Annual Reports, n.d.). Failure to comply with opioid practice regulations could result in a disciplinary action against a prescriber or clinician, including but not limited to probation, limitation, denial, fine, suspension, revocation

or permanent revocation of the professional practice license (MSMS, 2018). Additionally, failure to comply with opioid practice regulations may place patients at risk for medical error (Dy, 2016) or impair accessibility to opioids even when medically appropriate (Fehlberg, Broyles, Wu, & Halpern, 2018).

This DNP project has applicability to further compliant opioid practice in a variety of care settings nationwide. Especially in the current environment of large system, multistate practice, an organization may be subject to similar or conflicting laws and regulations from state to state. The framework developed in this project, an umbrella policy and identified tentacle policies with state specific variation maintained through a centralized system, offers an efficient strategy for multistate providers to ensure compliance. This system advances the quality of care by prescribing providers. To further the uptake of this approach for broader impact, I plan to seek publication in two nationally recognized journals, the Journal of Hospice & Palliative Nursing of the Hospice & Palliative Nurses Association, and Journal for Healthcare Quality of the National Association for Healthcare Quality. For dissemination to the hospice industry, I plan present at the National Association for Home Care & Hospice and the National Hospice and Palliative Care Organization conferences. In addition, I would like to explore with national nursing, hospice, and patient safety organizations an opportunity to do a workshop, a teleconference, or a webinar. Whether by synchronous or pre-recorded for asynchronous learning, this approach would further expand the accessibility of this framework for compliant opioid practice.

Limitations

The presence of COVID-19 PHE created a heightened awareness for anticipating and planning for failures or interruptions in the project before an adverse event occurs. Failure Mode and Effects Analysis (FMEA) is a structured way to identify and address potential problems

before they occur. If a FMEA was conducted before the project kicked off, resource allocation disruption, deviation of resources, a backup training mode, etc. could have been anticipated and planned for.

Conclusion

A review of current opioid regulations and development of opioid prescription, use, patient education, and disposal policies and practices will provide clarity to hospice and palliative care practitioners engaged in care of EOL advanced cancer and non-cancer patients. These policies will guide the hospice clinicians of their role and responsibility while caring for patients who are prescribed opioids at EOL.

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APPENDIX A

Evidence Table

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Albert, 2017	Symptom management at end of life	Clinical evidence	Evidence synthesis	Palliative medicine; Persons at the end of life	Review of symptoms experienced by the persons at their end of life, and treatment modalities (medications) to treat those symptoms.	Clinicians can help patients achieve comfort at end of life and death with dignity by effective symptom control through medication.
Bernard, 2018	Pain management and opioid epidemic	Clinical evidence	Evidence synthesis	Acute care and primary care settings; disabled veterans, cancer and non-cancer patients with pain	Review of use of opioids for pain management in the United States; Review of role of national organizations and pharma companies in promoting opioid use	Changing political landscapes supported escalation of opioid epidemic; Medical community is becoming increasingly aware of issues related with opioid use.
Bonnie, 2017	Burden of pain, pain management, opioid epidemic, & alternatives to opioids for pain	Clinical, legal, and policy evidence	Review of scientific literature to support U.S. Food and Drug Administration (FDA) regulatory decision making	Bibliographic databases, federal, state, and local agencies and organizations for guidelines,	Review of prescription opioid-related harms; Regulatory Strategies to Address Prescription Opioid-	Incorporate public health considerations into life-cycle of opioid drug development, oversight, and marketing, including regulatory decisions.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
	managem ent			and LexisNexis database; Pain conditions, Pharmacolo gical & non-pharmacolo gical pain managemen t, policy & cost of pain treatment, and impact of opioid epidemic on public health. Population with chronic pain	Related Harms	
Bonnie, 2019	Role of opioids in managing pain and disparitie s in access to pain managem ent	Peer reviewed commentary	Review of scientific literature, federal reports and initiatives on pain policy and global opioid regulations and access; and expert opinion.	Bibliograph ic databases, FDA and Institute of medicine (IOM) reports, Veterans Administrat ion and the Department of Defense (VA/ DoD) opioid safety initiative	Recommend ation for comprehensi ve opioid regulation and pain policy for treatment with opioids, clinician education, and for cultural assimilation of safe opioid use practices.	A comprehensive, population health–level strategy for pain management needs to be aligned with the opioid regulations and guidelines.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
				report, Centers for Disease Control and Prevention (CDC) opioid guidelines, and United States opioid regulatory policy. Population with chronic pain		
Brant, 2017	Breakthrough cancer pain	Systematic literature review.	A search of PubMed and CINAHL® databases was conducted using the Putting Evidence Into Practice (PEP) search procedure to identify literature regarding pharmacologic strategies for breakthrough cancer pain published from January 2006 to June	Forty-four studies provide evidence for the use of opioids for the management of breakthrough cancer pain - 6 systematic reviews/meta-analyses, 25 studies, and 3 clinical guidelines provide evidence for oral and transmucosal opioids; and 3	Adapting the evidence-based strategies that are recommended for treating breakthrough cancer pain could significantly decrease pain, and quality of life for patients with cancer.	Opioids are the mainstay of management for breakthrough cancer pain, however opioid doses should be individually titrated.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
			2016. These studies were then synthesized by the Oncology Nursing Society Putting Evidence Into Practice pain team.	studies and 3 guidelines provide evidence to give oral opioids for breakthrough cancer pain		
CDC, 2019	Opioid overdose and opioid prescription for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.	Guidelines	Access to safer and effective chronic pain treatment while reducing the number of people who misuse or overdose from these drugs.	Patient-centered clinical practices for patients with chronic pain who are prescribed opioids to manage pain.	Three main focus areas when prescribing opioid for managing chronic pain: Determining when to initiate or continue opioids for chronic pain; Opioid selection, dosage, duration, follow-up, and discontinuation; Assessing risk and addressing harms of opioid use	Essential discussion with patients about: Opioid alternatives; risks and benefits of opioid therapy; ways to mitigate patient risk; treatment for opioid use disorder

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Cleary, 2015	Impact of cancer-related pain, and gaps in its treatment	Background Information/Expert Opinion	Use of opioids for pain control in cancer patients experiencing pain	Patients diagnosed with cancer in acute & palliative care settings	Cancer-pain control through opioid use; Palliative care as a means to access to opioids for cancer pain treatment in low- & middle-income countries	Global efforts for effective cancer-pain treatment through "cornerstone trinity," are medication availability (including cost control), education, and policy reform.
DeWeerdt, 2019	United States opioid epidemic	Article synopses	Reasons for opioid epidemic in the United States (U.S.), and its spread to other countries.	Patients with acute or chronic pain, in cancer and non-cancer settings.	Impact of opioid overuse on U.S. health-care system, regulatory regime, culture and socio-economics.	A tight drug regulatory system is essential for evaluating the safety and effectiveness of drugs when used as directed. This can prevent the potential opioid misuse.
Dowell, 2016	Opioids for chronic pain	Guidelines	Opioids for chronic pain recommendations for primary care physicians	Chronic pain outside of active cancer treatment, palliative care, and end-of-life care; Primary care practices	Recommendations for primary care physicians about when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up,	• Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. If opioids are used, they should be combined with

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
					and discontinuation; and assessing risk and addressing harms of opioid use.	nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate. • medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.
Duthey, 2014	Access to opioid analgesics	Comparative analysis	Comparing the actual consumption of opioid analgesics with the calculated need for countries and World Health Organization regions in 2010 as compared with 2006.	Adequacy of consumption of opioid analgesics in countries around the world in patients with moderate and severe pain.	Calculate the morbidity-corrected needs per capita for opioid analgesics and the consumption for the top 20 Human Development Index countries. Calculate the number of people living in countries	The consumption of opioid analgesics remains inadequate in most of the world: 66% of the world population has virtually no consumption, 10% very low, 3% low, 4% moderate, and only 7.5% adequate.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
					at various levels of adequacy.	
Dy, 2016	Patient safety and end-of-life care	Critical appraisal	Synthesis of systematic reviews and additional research on improving patient safety and end-of-life care.	Palliative and end-of-life care	Compare Patient safety and end-of-life care's perspective on common issues in traditional patient safety frameworks; Current approaches in each field can inform the other; Patient safety at end-of-life comparison to patient preferences for life-sustaining treatment.	Understanding the comparable issues between patient safety and end-of-life care and their different perspectives, can benefit both fields learn and improve patient care in palliative and end-of-life care.
Fehlberg, 2018	Opioid crisis and end-of-life care	Policy review and synopses	Reactions to opioid crisis and impact on patients during their end-of-life with the appropriateness of their opioid prescriptions.	Palliative and hospice care patients experiencing pain at end-of-life.	Recent regulatory updates impacting access to pain management in palliative and hospice care patients.	Education and training for palliative care and hospice providers regarding appropriateness of opioid analgesics.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Gabbard, 2018	Substance use disorder (SUD) and hospice care	Peer reviewed commentary	Case review of SUD patient to develop understanding on how to deal with patients who have SUDs and uncontrolled pain.	Terminally ill cancer patient in an inpatient care setting.	Screening of patients with SUD, review of current guidelines, and treatment approaches for hospice patients in pain who have SUD.	Screen All Patients for SUDs; Complete a Comprehensive Pain, Opioid, and Social History in All Patients; Adapt Practices from SUD Treatment Programs to Hospice Patients with Active SUD; Communicate with Patients Identified to be Misusing Opiates; Increase Education of SUDs for Hospice Providers.
Garcia, 2013	Chronic pain, opioid abuse, and policy	Policy review and analysis	Review of scientific literature, federal reports and state regulations, and initiatives on pain policy for opioid regulations and access.	Problem of chronic pain and prescription painkiller abuse and overdose in public health	Inadequate treatment of pain in the U.S. and the subsequent rise of prescription painkiller abuse, misuse, and overdoses; Actions taken by states to regulate the prescribing	It is important to evaluate the impact opioid prescription policies are having, both in reducing painkiller abuse, misuse, and overdoses and on legitimate access to pain care.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
					of controlled substances.	
Hahn, 2018	Opioid epidemic and opioid policy	Expert commentary	Review and analysis of federal policies and funding to combat opioid crisis in the U.S.	U.S. communities impacted by overprescribing of opioids and the illegally produced heroin.	Align healthcare pain protocols to federal opioid policies, federal funding and programs; opioid addiction prevention, opioid addiction treatment, overdose, reversal, and recovery.	Presidential Opioid Crisis Plan needs sustained funding to impact communities that have been hit hard by the opioid epidemic. Nurses to advocate for Congress to address the recommendations of the Presidential Commission Report about opioid crisis, training of lay people and first responders to administer naloxone, and increasing access to treatment for our patients.
Harm reduction coalition, n.d.	Opioid overdose prevention	Report analysis and advocacy	Review of opioid overdose CDC report and advocacy to	Prescription and non-prescription drug overdose	Educating drug users about overdose recognition and response	Drug overdose deaths can be contributed to prescription and non-prescription drugs; drug

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
			prevent overdose deaths.	deaths in the U.S.	can prevent overdose deaths and reduce harm. Naloxone is a safe antidote for opioid overdose.	overdose can be prevented.
HHS, 2017	Opioid crisis	Federal policy declaration	Addressing the nationwide opioid public health emergency	Opioid crisis in the U.S.	Opioid crisis is a public health emergency and a top priority of the federal government.	Improve access to prevention, treatment, and recovery support services; and target the availability and distribution of overdose-reversing drugs
Howell, 2017	Prescription Drug Monitoring Program (PDMP)	Policy review and advocacy	Review of Missouri (MO) state opioid laws related to PDMP.	PDMP bills in the state legislature	Passing state bills to establish the PDMPs in the state of MO.	PDMP bill in the MO state legislature is still pending. There have been local efforts however to establish county-based PDMPs throughout the state.
IASP, 2017	Pain terminology	Terminology listing	Alphabetically arranges listing of pain related words	IASP Task Force on Taxonomy	A Current List of 35 pain terms with definitions and notes on usage	Pain terminology definitions are updated on a periodic and continual basis by IASP's pain experts.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Johnson, 2018	Opioid crisis	Case study	Interviews with public officials about county's opioid policies.	Suburban Northern Kentucky's three counties facing opioid crisis.	The public officials were asked questions regarding specific policies in their counties, their opinions on the causes of the opioid crisis, their assessment of the regional opioid crisis, and their views on the efforts of a variety of actors, including the city, state, and federal governments, the public, and civic organizations .	All three counties are addressing the problem using several tactics, including prevention, treatment, law enforcement, and long- term healthcare.
Katz, 2017	Cancer related breakthrough pain (BTcP)	Data analysis	A cross-sectional observational survey data analysis for a subset of patients with BTcP.	Community -dwelling adults with cancer and chronic pain.	For patients with cancer pain also experiencing breakthrough pain were surveyed for pain triggers, pain onset, and average	BTcP among community-dwelling patients with cancer continues to be a health burden and reveals opportunities for improvement.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
					and worst pain intensity during the preceding 24 hours, respectively, and high interference with activity, mood, ability to walk and work, social relations, sleep, and enjoyment of life.	
McCullough, 2018	Substance use disorder (SUD) treatment	Policy analysis	A review of Congressional opioid legislation for substance use disorder (SUD) treatment	SUD persons requiring treatment coverage under state Medicaid programs	The SUPPORT for Patients and Communities Act reauthorizes funding for state Medicaid programs for medication-assisted treatment (MAT) for opioid addiction and other SUD.	Although the MAT funding for SUD is a step in the right direction, long-term funding is needed to end the opioid crisis and sustain the results.
Mcginty, 2018	High-risk opioid prescribing practices	Mixed-methods study	A primary quantitative analysis to estimate the effects of the opioid laws	U.S. states that have enacted at least one of the multiple types of	To characterize the implementation and enforcement	The opioid epidemic is driven by high rates of opioid prescribing by

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
			enacted in states comparing to control pool states. The overarching goals of the study are on two primary sets of outcomes: (1) high-risk opioid pre-scribing patterns and (2) treatment of chronic non- cancer pain.	laws designed to curb high-risk opioid prescribing practices associated with opioid misuse, dependence, and mortality, including high-dose opioid prescribing, long-term opioid prescribing for acute pain, and overlapping opioid and benzodiazepine prescriptions.	of the four types of state laws to curb high-risk opioid prescribing practices and to evaluate the independent effects of those laws, accounting for variation in implementation and enforcement across states.	healthcare providers; Impact evaluation of implementation, enforcement, and outcomes of policies designed to curb high-risk opioid prescribing practices is needed; Inform the dynamic policy environment to pass, revise, implement, and enforce varied laws to address opioid prescribing each year.
Meldrum, 2016	Opioid epidemic	Expert commentary	Historical context of opioid prescription epidemic and resulting impact	Patients with chronic pain who are prescribed opioids to treat pain in last 3 decades.	Exploring the campaign for the long-term use of opioids in chronic (& non-cancer) patients.	Alternative treatment modalities to opioid medications are needed. Strict physician supervision is needed when opioids are prescribed for chronic pain.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
MSMS, 2018	Opioid epidemic and law	Policy analysis	A review of Michigan state opioid laws	Michigan state opioid laws for licensed prescribers of opioid medications to adults and minors.	Effective June 1, 2018, Michigan state opioid laws regarding informed consent before prescribing opioid medications, automated prescription system checks, limitation on prescribing, patient-prescriber relationship, SUD, and MAT.	Failure to comply with the Michigan state opioid laws could result in the disciplinary actions against a physician's license. Non-compliance could result in disciplinary action by the Michigan Board of Medicine.
National Cancer Institute, n.d.	Cancer terminology	Terminology listing	**Alphabetically arranged dictionary of cancer terms**	National cancer institute dictionaries	A Current List of 8,680 terms related to cancer and medicine.	A dictionary of cancer and biomedical terms defined in non-technical language. Terms and definitions are reviewed by a multidisciplinary panel of reviewers and new terms are added each month.
NCSL, 2019	Opioid overdose epidemic and laws	Policy review	A review of U.S. state opioid laws	Misuse of prescription and illicit opioids in	CDC guidelines and laws related to	States have enacted laws to tackle prescription

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
				the community	opioid prescription regulation, prescription drug monitoring programs, access to naloxone, pain clinic regulation, provider education and training.	drug misuse , addiction and overdose through the laws related to prescription drug monitoring programs, access to naloxone, pain clinic regulation, provider education and training
National Science and Technology Council, 2018	National opioid crisis	Federal committee report	Federal roadmap for research & development (R&D) to curb the national opioid crisis in the U.S.	U.S. communities impacted by opioid public health emergency.	Federal opioid fast track action committee (FTAC) organized its efforts in a Roadmap, and identified seven areas of R&D: (1) the Biology and Chemistry of Opioid Addiction and Pain; (2) Non-Biological Contributors to Opioid Addiction; (3) Pain Management ; (4) Prevention of Opioid	For long-term resolution of the opioid crisis, the federal departments and agencies doing substantial research efforts related to the opioid crisis need to strategically coordinate those efforts. This step is critical to ensure that the Administration delivers the comprehensive science response that the opioid crisis demands. .

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
					Addiction; (5) Treatment of Opioid Addiction and Withdrawal; (6) Overdose Prevention and Recovery; and (7) Community Consequences of Opioid Addiction. The research recommendations generated by the FTAC in each of these areas, as well as an eighth section that includes recommendations on ways to enhance coordination, are summarized in this report.	
National Science and Technology Council, 2019	National opioid crisis	Federal committee report	Federal roadmap for research & development (R&D) to curb the national opioid crisis in the U.S.	U.S. communities impacted by opioid public health emergency.	Based on the feedback from general public and healthcare community in November 2018, Federal	For long-term resolution of the opioid crisis, the federal departments and agencies doing substantial research efforts related to the

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
					opioid fast track action committee (FTAC) organized a revision to its efforts in a Roadmap, and identified seven areas of R&D: (1) the Biology and Chemistry of Opioid Addiction and Pain; (2) Non-Biological Contributors to Opioid Addiction; (3) Pain Management; (4) Prevention of Opioid Addiction; (5) Treatment of Opioid Addiction and Withdrawal; (6) Overdose Prevention and Recovery; and (7) Community Consequence	opioid crisis need to strategically coordinate those efforts. This step is critical to ensure that the Administration delivers the comprehensive science response that the opioid crisis demands. FTAC provided a forum for federal interagency discussions that may lead to closer coordination of strategy and activities. .

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
					s of Opioid Addiction. The research recommendations generated by the FTAC in each of these areas, as well as an eighth section that includes recommendations on ways to enhance coordination, are summarized in this report.	
Painter, 2017	Opioid crisis and healthcare reform	Policy analysis	A review of opioid policy, current healthcare reform and its impact on opioid crisis, and considerations for nurse on the frontlines.	Nurses who provide assessment for patients with opioid use histories; Affordable care act (ACA) and federal, state, and local opioid policy changes.	Local policy about availability of naloxone to prevent opioid overdose deaths; Provision of MAT for individuals with SUD who have health insurance under ACA; Nurses' involvement in community based opioid overdose prevention'	Need for continued resources to combat the ongoing epidemic, and sustain prevention efforts; Nurses as healthcare leaders to break the stigma of opioid addiction, and support vulnerable populations through Interprofessional collaboration for treatment, education, and advocacy.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
					education, and advocacy programs.	
Parker, 2018	Opioid epidemic	Policy review and advocacy	Most common state policy responses and review to better understand the most prevalent state responses to the opioid crisis.	U.S. communities impacted by opioid public health emergency.	Six primary approaches states have taken to combat the opioid epidemic: opioid prescribing policies, opioid education in the communities, MAT for SUD, overdose prevention, disciplinary actions and penalties.	An evaluation of state approaches to combat opioid crisis is needed, to understand the impact of policy effectiveness, funding resources and sustainability of the efforts.
Prescription drug abuse policy system, 2019	Opioid overdose	Policy analysis	A review of Good Samaritan overdose prevention laws.	Opioid overdose bystanders in the U.S. communities.	States have enacted "Good Samaritan" laws that create immunities or other legal or broad protections for people who call for help in the event of a drug overdose.	By enacting Good Samaritan laws, states are making an effort to prevent opioid overdose deaths, and reduce stigma associated with treatment for SUD.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Prescription drug abuse policy system, 2019	Opioid overdose	Policy analysis	A review of opioid overdose prevention laws.	Opioid overdose deaths in the U.S. communities.	Administering naloxone hydrochloride ("naloxone") can reverse an opioid overdose and prevent the unintentional deaths.	By enacting naloxone laws, states are making an effort to prevent opioid overdose deaths by making naloxone easily and readily available in the common household.
Prescription drug abuse policy system, 2019	Opioid overdose deaths	Policy analysis	A review of pain management clinic laws.	Opioid overdose deaths in the U.S. communities.	Prescriptions for opioids are involved in almost half of all opioid overdose deaths; state laws regulate pain management clinics, clinic owners, and the physicians that work at the clinics.	By enacting pain management clinic laws, states designate certain medical practices that provide management services as pain management clinics and subject these clinics to extra regulation.
Prescription drug abuse policy system, 2019	Opioid misuse and overdose deaths	Policy analysis	A review of opioid prescribing practice laws.	Opioid misuse and overdose deaths in the U.S. communities.	Prescription drug monitoring programs (PDMPs) collect patient-specific prescription information in centralized databases.	By funding PDMPs, states continue to commit to reduce the misuse of controlled medicines.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
S.2680, 115th Congress, 2018	Opioid public health emergency	Policy analysis	Federal bill to address the national opioid crisis.	Opioid misuse and overdose deaths in the U.S. communities.	Opioid Crisis Response Act of 2018, S. 2680 includes laws for pain research; controlled substance safety; treatment and recovery from opioid overdose, misuse, and SUD; impact of opioid crisis on workforce and economy; overdose prevention; and education.	By enacting federal opioid laws, states are making an effort to prevent opioid overdose deaths.
SAMHSA, 2017	Opioid overdose deaths	Policy review and advocacy	A review of Good Samaritan overdose prevention federal laws and state policies.	Opioid overdose bystanders in the U.S. communities.	Overdose Good Samaritan laws provide legal protections for individuals who call for emergency assistance in the event of a drug overdose. However, lack of awareness	Raising awareness by educating the prescribers, healthcare workers, law enforcement personnel, criminal justice personnel, prescription and non-prescription drug users, and the general public about the state's Overdose Good Samaritan

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
					and understanding of these laws may be limiting their effectiveness in the community and preventing the criminal justice system from fully observing them.	law requirements and limitations, will help full actualization of the law.
SAMHSA, 2018	Opioid overdose public health emergency	Toolkit	A review of opioid use disorder facts, guidelines, opioid laws, and resources for opioid use disorder survivors.	Persons who have opioid use disorder, their families, and the practitioners treating opioid use disorders.	For drug users, their families, and prescribers, the toolkit describes: • strategies to prevent overdose deaths, • essential steps for first responders, • medical, billing, and legal considerations for prescribers, • safety advice, and • resources and available	The opioid overdose survivors need the support of family, friends, prescribers, and community resources to recover and sustain the results.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
					support networks	
Saunders, 2018	Opioid use disorder	Systematic review	A review of published and grey literature to identify federal and state policy strategies regarding opioid misuse among pregnant women.	Opioid misuse during pregnancy and treatment of opioid use disorder around the time of childbirth.	Current federal and state laws that impact women before pregnancy, during pregnancy, at birth, and postpartum were reviewed to identify gaps and challenges related to treatment efforts of opioid use disorder.	Gaps were identified in current policies - there's limited attention to prevention of opioid misuse among reproductive-age women, and there's a lack of policies addressing opioid misuse among postpartum women. There do exist access to care barriers for women who misuse opioids, including provider shortages, lack of resources, stigma, and fear of legal consequences. It is imperative that policymakers address the opioid epidemic, the unique needs of pregnant and postpartum women and barriers to

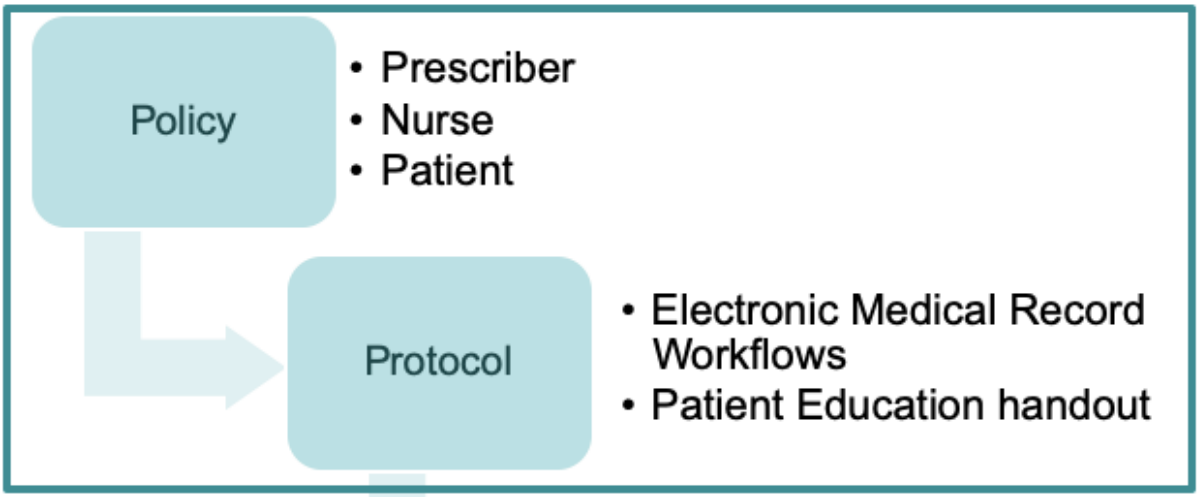
Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
						treatment should be addressed.
Scholten, 2019	Access to opioid analgesics	Meta-analysis	Statistics for 18 controlled opioid medicines that are primarily used as analgesics was used for the study. Quantitative methods were used to summarize the results using Adequacy of Opioid Consumption (AOC) Index.	International Narcotics Control Board's Opioid consumption statistics database from 1990 to 2015 were used for this research project, containing the annual consumption by country and by substance.	Monitoring adequacy of opioid consumption is important to identify countries that have insufficient access to adequate pain management.	Access to opioid analgesic consumption continues to be inadequate in many countries around the world and improvement of adequacy is limited to a number of countries and that policy efforts do not manage to keep pace with the increasing world population.
Tompkins, 2017	Chronic pain	Evidence synthesis	Critical appraisal, evaluation and synthesis of medical literature, research studies and articles regarding pain treatment and pain regulations.	Chronic pain in Americans and need for pain treatment	Narrative about chronic pain, its pharmacologic (opioid and non-opioid analgesics) and alternative treatment, and healthcare practitioner chronic pain management practice	To manage chronic pain, non-opioid medications, and non-pharmacologic treatment modalities need to be explored, including safety and efficacy of the alternative treatments and , needs and barriers to utilization of

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
					considerations.	non-opioid therapies.
Weber, 2019	Opioid monitoring	Policy review and advocacy	A review current state of Missouri's prescription drug monitoring program (PDMP) legislature.	Patient advocates, politicians, experts and members of the medical community of the state of Missouri.	Missouri has not been able to pass PDMP legislation in last 7 years.	Missouri state republican conservative caucus has filibustered the passing of PDMP legislation in state senate. Medical and pharmacy communities have voluntarily opted for PDMP in Missouri's 72 jurisdictions covering 84% of the population.
WHO, 2018	Cancer pain	Guidelines	Evidence-based guidance on utilization of pharmacological and radiotherapeutic management for cancer pain.	Cancer pain in adolescents, adults, and older adults.	Provide pain management guidance to healthcare providers for relief of cancer pain. Provide policy guidance for opioids and prescribing regulations for effective and safe cancer pain management.	For safer cancer care and for improving quality of life of cancer patients experiencing pain, cancer pain management should be a part of cancer care treatment plan.
WHO, 2019	Essential medicines and health products	Current listing and databases of essential medicines	Chronologically arranged essential	The WHO Model Lists of Essential Medicines for adults	The list is developed based on recommendations made by	The WHO Model Lists of Essential Medicines has been updated

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
			medications lists	and children, from the year 2002 to current.	the WHO Expert Committee on the Selection and Use of Essential Medicines for the Essential Medicines Lists update, including a database of antibiotics.	every two years since 1977. There are separate lists of essential medications for adults and children.
WHO, 2019	Essential medicines and health products	Current listing of essential medicines	Alphabetically arranges listing of essential medications	The 2019 WHO Model Lists of Essential Medicines for adults and children.	The list is developed based on recommendations made by the WHO Expert Committee on the Selection and Use of Essential Medicines for the Essential Medicines Lists update.	The core list presents a list of medicine needs for a basic health-care system, listing the most efficacious, safe and cost–effective medicines for priority conditions. The complementary list presents essential medicines for priority diseases, for which specialized diagnostic and/or specialist care is needed.

APPENDIX B

Aim 2: Development of opioid policy and clinical documentation protocol



APPENDIX C

Policy and Procedure Development Guidelines

(Reprinted from Policies and Procedures for Healthcare Organizations: A Risk Management Perspective. Retrieved from https://www.psqh.com/analysis/policies-and-procedures-for-healthcare-organizations-a-risk-management-perspective/ December 2019)

Recommendation	Rationale
Define all terms used within the policy.	It is useful to put these definitions at the beginning of the policy. If terms are not defined, they may be misconstrued by staff and/or when later scrutinized by plaintiff lawyers.
Refrain from using superlative words or statements, such as: a) Highest, safest, best (level of care) b) Assure, ensure (preferable to use "to promote")	The presence of superlative adjectives is sometimes alleged by plaintiff lawyers to be a "guarantee" of a certain outcome.
Exercise caution when using absolutes such as shall, must, or do not unless intended as such.	Many circumstances allow for clinical judgment.
Select a simple, recognizable name for the policy.	Naming a policy "Chain of Command Policy" is preferable to naming it, "Disagreement over patient care." Staff will have an easier time locating a policy with a familiar name.
Combine separate policies on the same subject into one policy. If it becomes lengthy, create a table of contents so the user can easily locate specific sections.	For instance, the policy for medical screening examinations, transfer in/out, reporting EMTALA violations, etc. should appear in a single EMTALA policy.
Use the active rather than the passive voice when writing specific procedure action steps.	Passive voice: "The specimen container should be labeled." Active voice: "Place a label on the specimen container."
Ensure responsibility for carrying out each action step is explicitly stated, not implied.	Each section should have two columns: the one on the left outlines the action to be taken, and the one on the right says who is responsible for carrying out each step.
Obtain the sign-off of all stakeholders (domain leaders) affected by each policy, as well as each oversight committee or entity that reviewed and approved of it (e.g.. Medical Executive Committee [MEC]).	It is not uncommon to see "nursing" policies that outline actions an independently credentialed physician is expected to take. Any policy that outlines medical staff responsibilities warrants their input during development and subsequent reviews. Medical staff members also need to know where to access those policies.
Require each approving entity or person to sign off on each individual policy. In years past, paper policy manuals often included a "cover sheet" as a sign-off page, which showed the date of approval and signature of the approving leader, in lieu of him/her signing each policy.	Cover sheets for sign off are not effective for electronic documents.

Recommendation	Rationale
Note the date of origin of the policy and each subsequent review or modification date within the body of the policy, typically on the last page near the sign-offs: Date of origin: ____ Review date: ____ Review date: ____	Pay particular attention to how the approvals for subsequent policy updates are documented in the electronic version of the policy.
Establish naming and numbering conventions for use across the health system.	Number all pages, reflecting the total number of pages as well: page 1 of 5, 2 of 5, etc. Put the policy title/number in the header of each page.
Note other policies on a similar subject that may be useful at the end of the policy, for cross-reference purposes. Incorporate any related form(s) or computer screen images referred to in a policy	For example, the disclosure policy should cross-reference adverse event reporting policy, the patient complaint/grievance policy, and the bill hold/adjustment policy. Also for example, the EMTALA transfer form should be a part of the EMTALA policy.
Cite specific federal or state statute(s) that are the basis for a policy or procedure with any other references.	It may also be helpful to put a URL link to those statutes.
At the end of the document, note evidence-based resources referred to when developing the policy. Some organizations simply place a list of resources as an attachment to each policy, so that it is not a part of the actual, page-numbered policy document.	Noting the referenced resources in each policy has both advantages and disadvantages. The advantage is that readers are aware of a professional source for more information on that subject. Another advantage is that it demonstrates the policy was developed with awareness of recognized professional guidelines and evidence-based best practices. However, potential risks arise when: a) the organization's policy differs from the cited professional guidelines or omits some key element noted in those guidelines; b) If the cited professional guideline is updated following issuance of the policy, and the organization has not updated the policy accordingly. Doing so means that if the organization has to produce the policy during discovery, the list of resources need not be turned over, since it "was not part of the policy itself".
Avoid under-specifying: Put all essential elements in the policy.	For instance, stating that "X action shall be taken" does not specify which staff member is responsible for carrying out the task.
Avoid developing policies that outline actions that are more rigorous than the typical "standard of care."	If a hospital implements a policy that goes beyond what is the prevailing practice in the industry, the organization will be held to the higher standard.
Use caution when approving a policy on a specific topic or practice that simply states that staff shall	Doing this implies: a) the cited book is the most updated authoritative source on that subject; b) the

Recommendation	Rationale
adhere to the practices outlined in “ABC Textbook” (and does not outline the organization’s own steps). Citing a reference as the policy may be appropriate in a narrow range of situations. For example, the American College of Radiology publishes an evidence-based, comprehensive “Use of Contrast Media Manual” with regular updates. Rather than develop its own policies on this subject (which would likely be shorter and oversimplified when compared to this manual), a hospital-based radiology department may wish to endorse the staff’s use of this manual, with the proviso noted to the right.	responsible domain leaders have reviewed the book from cover to cover and have “endorsed” all of its contents; c) staff members have ready access to that resource (at all times); and d) there is a process in place to monitor when the ACR issues a revised version of this manual, so the organization does not continue to use guidelines that may have changed.

APPENDIX D

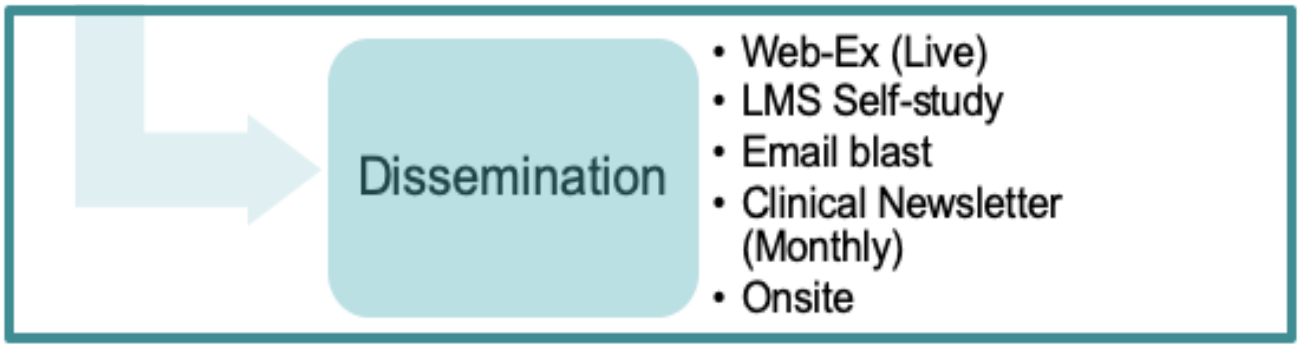
EMR Opioid Documentation Template

Opioid documentation in EMR software will be designed for convenience of data extraction to evaluate physicians, nurse practitioners, and nurses for compliance with the policy. The major EMR categories will be:

- Type of opioid prescription
    - Long acting
    - Short acting
- Case manager nurse, patient/family caregiver, & prescriber communication
    - Yes
        - Communication note
    - No
- Non-pharmacological & alternative options
    - Offered
        - Documentation of options offered & outcome
    - Not offered
        - Document why not offered
- Patient education
    - Yes
        - Communication note
    - No
        - Describe why?
- Opioid Reconciliation
    - Yes
        - Communication note
    - No
        - Describe why?
    - Not applicable
- Opioid disposal
    - Yes
        - Communication note
    - No
        - Describe why?
    - Not applicable

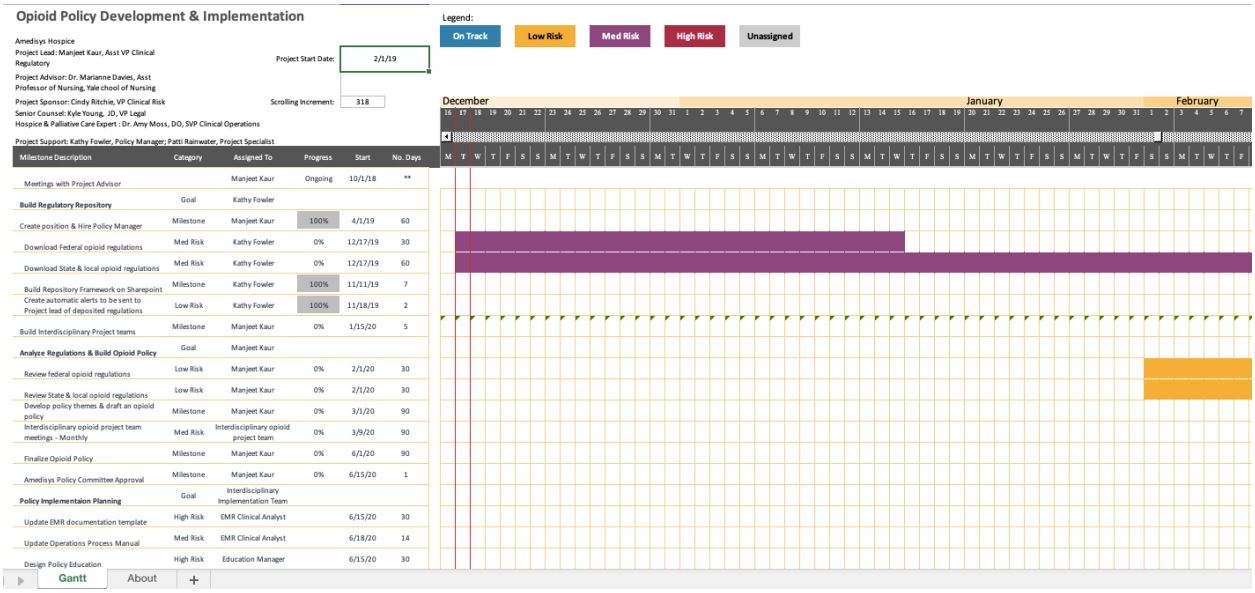
APPENDIX E

Aim 3: Dissemination of policy and implementation of protocol



APPENDIX F

Timeline of the DNP Project



Task	Start Date	End Date	Duration
Meetings with DNP Project Advisor (ongoing)	10/1/18	1/31/21	485
Create position & Hire Policy Manager	1/1/19	4/1/19	90
Download Federal Opioid Regulations	12/17/19	1/17/20	30
Download State & Local opioid regulations	12/17/19	1/17/20	30
Build Repository Framework on Sharepoint	11/11/19	11/18/19	7
Create automatic alerts to be sent to Project lead of deposited regulations	11/18/19	11/20/19	2
Build Interdisciplinary Project teams	1/20/20	3/20/20	59
Review federal opioid regulations	6/1/20	6/30/20	30
Review State & local opioid regulations	6/1/20	6/30/20	30
Develop policy themes & draft an opioid policy	7/1/20	7/20/20	20
Interdisciplinary opioid project team meetings - Monthly	3/20/20	11/20/20	240
Finalize Opioid Policy	7/25/20	8/07/20	14
Amedisys Policy Committee Approval	8/07/20	8/07/20	1
Update EMR documentation template	8/7/20	8/31/20	25
Update Operations Process Manual	8/7/20	8/31/20	25
Design & Build Policy Education	8/7/20	8/31/20	25
Send E-mail blast of policy implementation	8/15/20	8/15/20	1
Web-Ex policy education sessions	9/1/20	11/30/20	61
Online LMS policy education sessions	9/1/20	11/30/20	61
On-site policy education	9/1/20	11/30/20	61
Web-Ex attendance (Outcome Evaluation)	9/1/20	11/30/20	61
Online LMS policy education attendance (Outcome Evaluation)	9/1/20	11/30/20	61
On-site policy education attendance (Outcome Evaluation)	9/1/20	11/30/20	61
EMR Compliance Report (Outcome Evaluation)	9/30/20	12/5/20	66
Manuscript Submitted to Peer-Reviewed Journal or Conference	1/1/21	1/31/21	31