

OPIOID CONSENTING: A NOVEL PROGRAM TO ADDRESS OPIOID SAFETY

by

Kalekia Adams

Copyright © Kalekia Adams 2020

A DNP Project Submitted to the Faculty of the

COLLEGE OF NURSING

In Partial Fulfillment of the Requirements

For the Degree of

DOCTOR OF NURSING PRACTICE

In the Graduate College

THE UNIVERSITY OF ARIZONA

2020

THE UNIVERSITY OF ARIZONA
GRADUATE COLLEGE

As members of the DNP Project Committee, we certify that we have read the DNP project prepared by Kalekia Adams, titled Opioid Consenting: A Novel Program to Address Opioid Safety and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.

Heather L. Carlisle Date: Jan 8, 2021
Heather L. Carlisle, PhD, DNP, AGACNP, FNP, ACHPN

Kimberly D. Shea Date: Jan 8, 2021
Kimberly D. Shea, PhD, RN, CHPN

Doneen Grimm Date: Jan 11, 2021
Doneen Grimm, PharmD

Final approval and acceptance of this DNP project is contingent upon the candidate's submission of the final copies of the DNP project to the Graduate College.

I hereby certify that I have read this DNP project prepared under my direction and recommend that it be accepted as fulfilling the DNP project requirement.

Heather L. Carlisle Date: Jan 8, 2021
Heather L. Carlisle, PhD, DNP, AGACNP, FNP, ACHPN
DNP Project Committee Chair
College of Nursing



ARIZONA

ACKNOWLEDGMENTS

To Doneen Grimm, PharmD, for her gracious collaborative efforts, ensuring the feasibility and success of this project. Thank you.

DEDICATION

To black women, who have secretly known they were magical all along, despite the world's disbelief, shrinking and hiding in order to not offend.

I see you. I believe in you. I am you.

TABLE OF CONTENTS

LIST OF FIGURES	7
LIST OF TABLES	8
ABSTRACT.....	9
INTRODUCTION.....	11
Background Knowledge and Significance	11
Local Problem	14
Arizona’s Opioid Crisis	14
Opioid Consent Program	17
Intended Evaluation.....	18
Project Purpose	18
Project Question.....	19
Project Objectives	19
Theoretical Framework	22
Literature Synthesis.....	24
Evidence Search	24
Comprehensive Appraisal of Evidence	24
Criticisms of narcotics contracts.	24
The need for narcan as a proxy for oversedation.	26
Pressures to prescribe.....	28
Strengths of Evidence	29
Weaknesses of Evidence	29
Gaps and Limitations	30
METHODS	30
Setting.....	30
Project Design.....	31
Model for Evaluation	32
Ethical Considerations.....	38

TABLE OF CONTENTS - Continued

RESULTS	39
Outcomes	39
DISCUSSION	42
Interpretation	42
Implications (Practice, Education, Research and Policy)	45
Limitations	46
Impact of COVID-19	47
DNP Essentials Addressed	48
 APPENDIX A: DIGNITY HEALTH SITE APPROVAL/AUTHORIZATION LETTER	49
APPENDIX B: THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD APPROVAL LETTER.....	51
APPENDIX C: LITERATURE REVIEW GRID.....	53
 REFERENCES	64

LIST OF FIGURES

Figure 1	<i>Dignity Health Opioid Consent</i>	20
Figure 2	<i>Kurt Lewin’s Change Theory Adopted for Opioid Consent Program</i>	23
Figure 3	<i>CDC Framework for Program Evaluation in Public Health</i>	33
Figure 4	<i>Total of Monthly Opioids Prescribed Over Time</i>	43

LIST OF TABLES

Table 1	<i>Logic Model for Opioid Consenting Program</i>	36
Table 2	<i>Pre-Implementation Period Opioid Prescription Frequencies</i>	39
Table 3	<i>Post-Implementation Period Opioid Prescription Frequencies</i>	40
Table 4	<i>Descriptive Statistics of Prescription Opioids</i>	40
Table 5	<i>Inferential Statistics of Prescription Opioids</i>	41
Table 6	<i>Pre/Post Period Frequencies of Narcan Administrations</i>	41
Table 7	<i>Inferential Statistics of Narcan Use.</i>	42

ABSTRACT

Purpose. The purpose of this program evaluation was to determine the impact of St. Joseph's opioid consent initiative on naloxone (Narcan) use and opioid prescribing patterns at discharge in accordance with recommendations and strategies set forth by the CDC and ADHS to increase opioid patient safety.

Background. Opioids are commonly used in managing moderate to severe pain in the hospital setting (Costello, 2015). In the United States (US), opioids are the most common drug class of prescriptive medication (Stepan et al., 2019). Coincidentally, opioids are classified as a leading cause of death in individuals under 50 years of age in the US with overdose fatalities from opioid use steadily increasing over the last 20 years across the country (National Institute on Drug Abuse [NIDA], 2015; Stepan et al., 2019). In Arizona, more than two people die each day because of opioid overdose (ADHS, 2020). Since 2017, and for each year thereafter, Maricopa County has consistently reported the highest number of verified overdose cases for commonly prescribed opiates (ADHS, 2020). St. Joseph's hospital developed an opioid consenting program to attempt to address prescription opiate safety in the community by targeting patient's disembarking the acute setting by offering opioid educational awareness for informed decision making regarding the inclusion of opioids in their care regimen at discharge.

Methods. A formative program evaluation using pre and post outcome measurement comparisons to examine the effect of opioid consenting on documented Narcan administrations and discharge opioid prescriptions six months before and after program implementation.

Results. Opioid prescriptions from the pre-implementation period (Mean = 1039.18, SD = 1445.09) decreased significantly, $Z = 2.7136$, $p = .00666$ compared to the post-implementation

period (Mean = 674.73, SD = 1045.09). The difference in Narcan use from the pre-implementation period (Mean = 85, SD = 90.51) and post-implementation period (Mean = 96.5, SD = 105.36) was not significant, $Z = 1.41421$, $p = .1573$, $\alpha = 0.05$.

Conclusions. The significantly decreased number of opiate prescriptions cannot solely be attributed to initiation of the opioid consent program due to indeterminable effects of multiple unmeasured confounding factors. Further evaluation is warranted.

INTRODUCTION

Pain plays an essential role in the overall experience of patient care (Calcaterra et al., 2016). Opioid analgesics are commonly used and highly effective in managing moderate to severe pain (Costello, 2015). However, the benefits and widespread availability of opioids are not without their risks and consequences. This facet of opioid use potentially places individuals at an increased risk for adverse outcomes, including addiction and even death (Costello, 2015). The ever-growing abuse of opioids, overdose, and subsequent deaths, collectively referred to as the *Opioid Epidemic*, taking place across the United States (US) over the last two decades is evidence of this knowledge deficit (Stepan et al., 2019). Therefore, it is imperative that providers and consumers have a complete understanding of opioids' safety to prevent harm related to use.

Background Knowledge and Significance

Globally, North America ranks first as the largest consumer of prescription opioids (Moride et al., 2019). In the US, opioids are the most common drug class of prescriptive medication (Stepan et al., 2019). Coincidentally, opioids are classified as a leading cause of death in individuals under 50 years of age in the US (Stepan et al., 2019). According to the National Institute on Drug Abuse (NIDA) (2015), overdose fatalities resulting from opioid use across the country have steadily increased over the last 20 years. In 2017, of the 70,237 US documented overdose deaths, 68% involved an opioid (Wilson et al., 2020). The following year, in 2018, that number increased to 70% (Wilson et al., 2020). Previously, in the period from 2016 to 2017, the total number of deaths involving all opioids and synthetic opioids increased as well (Wilson et al., 2020). A Centers for Disease Control and Prevention (CDC) vital signs report reveals emergency department (ED) visits for opioid overdose increased 30% across the country

from July 2016 to September 2017, with more than 140,000 suspected opioid-related overdose visits to the ED (Vivolo-kantor et al., 2018). Subsequently, an Agency for Healthcare Research and Quality (AHRQ) (2018) statistical briefing reports the national rate of opioid-related inpatient hospitalizations increased by 64% from 2005 to 2014, approximately/totaling 225 hospitalizations per 100,000 people. Most recently, data reveals this value to be 299.7 per 100,000 people (Healthcare Cost and Utilization Project [HCUP], 2020). Costs associated with opioid misuse in the US are estimated at \$78.5 billion annually; this value includes healthcare, loss of productivity, addiction treatment, and legal involvement costs (Florence et al., 2016).

Throughout the country, patient-centered mitigation efforts have been implemented and studied, commonly including various legislation aimed at reducing prescription opioid access in numerous states, including Texas, Oregon, and Florida (Moribe et al., 2019). In regards to prescriber directed interventions, risk evaluation and mitigation strategy (REMS) programming for all extended-release (ER) and long-acting (LA) opioids has been in existence since 2012 in the US; as well as updates to *the Blueprint for Prescriber Education of ER-LA Opioids* in 2018 by the Food and Drug Administration (FDA) (Moride et al., 2019). Likewise, the Secretary of Health and Human Services released the secretary's *Opioid Initiative* geared towards reducing mortality and addiction from opioid abuse employing reforming opioid prescribing practices, increasing access to Narcan (or naloxone, an opioid reversal drug), and expanding access to medication-assisted treatment (MAT) for opioid use disorder (NIDA, 2015). While considerable efforts, such as those mentioned above, have been made at both the state and federal levels to slow epidemic progression, multiple organizational databases have shown that the epidemic persists nationally (Moride et al., 2019).

The current state of misuse and addiction to opioids, including prescription drugs, heroin, and synthetic opioids, is a nationwide health concern of endemic proportions with origins dating back to 1980 (Office of National Drug Control Policy [ONDCP], 2017). At that time, an article published by the *New England Journal of Medicine*, considered low quality by modern research standards, purported addiction as a rare occurrence in patients receiving narcotics (Porter & Jick, 1980; Leung et al., 2017). This article would continue to be cited over 600 times in later publications (ONDCP, 2017). In the years that followed, related research reported results of a similar unsubstantiated vein, describing opioid maintenance therapy as a safer and superior option compared to surgery or conservative treatment modalities in patients (Portenoy & Foley, 1986). In a lexicon devoid of high-quality research demonstrating opioid's potential harms, popularity grew for these types of works, to the extent that federal and regulatory agencies accepted them as truths (ONDCP, 2017).

Additional contributory factors for the opioid crisis include large scale production of potent oral opioids, far-reaching access to illicit and inexpensive heroin, increasingly potent fentanyl and its/fentanyl analogs, the transition from prescription opioid misuse to heroin and fentanyl use, and the advent of pressed pill production containing lethal doses of fentanyl and other synthetics (ONDCP, 2017). These various factors impacted the opioid crisis in a compounding manner over time. Initially, the increase in opioid prescribing that was a commonplace practice in the 1990's lead to increases in the number of deaths secondary to overdose (National Institutes of Health [NIH], 2020). Roughly 21-29% of patients prescribed opioids for chronic pain misuse them, with approximately 8 to 12% developing an opioid use disorder (Vowles et al., 2015). The next phase began in the early 2000s with the increase in

overdoses related to heroin use. Individuals who report having misused prescription opioids, 4-6% of them transitioned to heroin, with roughly 80% of heroin users revealing that they first misused prescription opioids (Carlson et al., 2016). Lastly, around 2013, synthetic opioids growing popularity, especially those of the illicit fentanyl variety, caused an additional uptrend in opioid overdose-related deaths (NIH, 2020).

Unfortunately, pain is frequently an unavoidable facet of acute illness. Uncontrolled pain has multiple negative consequences on patient outcomes, including anxiety, depression, respiratory infections, myocardial infarct, thromboembolic events, and sleep impairment (Pozek, De Ruyter, & Khan, 2018). Accordingly, pain management is a mainstay of care provision, serving as a longstanding, quality indicator metric for patient care, prompting providers to ensure adequate assessment and treatment of pain (Calcaterra et al., 2017). Thus, the use of opioids and their efficacious mitigation of pain cannot be altogether evaded; rather, current and aspiring healthcare providers are charged with deciphering and practicing the safest methods of use for opioids in order to help and not harm patients. This aspect of care will undoubtedly be a part of future AGACNP practices as well.

Local Problem

Arizona's Opioid Crisis

In response to rising opioid-related deaths in the state of Arizona, Governor Doug Ducey declared an official state of emergency on June 5, 2017, initiating a call for action in addressing opioid overdose and (preventing opioid) addiction for the state (Arizona Department of Health Services [ADHS], n.d.). Subsequent legislation was passed, including the *Opioid Action Plan* and the *Arizona Opioid Epidemic Act*, to combat this local opioid crisis. The original *Opioid*

Action Plan consisted of 12 specific recommendations and 50 action items intended for use by state-level agencies and organizations, created by a collaboration between the ADHS, the Governor's Office, and the Arizona Health Care Cost Containment System (AHCCCS). The plan called for new reporting mandates for suspected overdose deaths, and pharmacist dispensed Naloxone data, updates to the *Arizona Opioid Prescribing Guidelines*, creating new rules for licensed care facilities, and training law enforcement in the use and distribution of naloxone (ADHS, n.d.). Items included in the second *Opioid Action Plan, Version 2.0*, uphold opioids as the leading culprit behind overdose and death but also highlights continuing efforts to improve access and quality of treatment for substance abuse in general, eliminating stigmas, promoting prevention and early recognition, and better data quality (ADHS, n.d.).

On May 29, 2018, Governor Ducey culminated in emergency response efforts, calling for an end to the previously established "state of emergency" (Ducey, 2018). While much has been done in regards to primary prevention aims of reducing undue opioid exposure, trends for overdosing and deaths due to opioids continue to rise (Calcaterra et al., 2016). According to the ADHS (2020), more than two people die each day because of opioid overdose in the state of Arizona. The 2018 sum of reported deaths attributed directly to opioids in Arizona equated to 1,167, a 21.7% increase in opioid deaths from the previous year (ADHS, 2018). Since 2017, and for each year thereafter, Maricopa County has consistently reported the highest number of verified overdose cases for commonly prescribed opiates, including fentanyl, morphine, methadone, oxycodone, tramadol, and other prescription opiates (ADHS, 2020).

As of May 1, 2020, for all individuals receiving an opioid prescription in the state of Arizona, the average morphine milligram equivalent (MME) daily dosage is 43.2 (ADHS).

MME assigns a value to various opioid drugs based on their relative potency (CDC, 2019). Current research states that individuals taking morphine milligram equivalent doses greater than or equal to 50 MME per day potentiates the risk for overdose two-fold in comparison to individuals using less than 20 MME daily (CDC, n.d.). Furthermore, a Veterans Health Administration study found that of all patients receiving opioids over a five year period, those who died of opioid overdose were prescribed an average of 98 MME daily (CDC, n.d.). To date, 5,246 deaths have been attributed to opioid overdose, with more than 40,000 non-fatal suspected opioid overdoses in Arizona since 2017 (ADHS, 2020). For the same period, more than 23,986 doses of Naloxone have been administered with greater than 80,000 doses dispensed (ADHS, 2020).

Most notably resultant from the *Opioid Action Plan* was the enactment of the *Arizona Opioid Epidemic Act* in January 2018 with its *Opioid Enhanced Surveillance* advisory. Under this mandate, healthcare providers, emergency medical services, and law enforcement are now required to provide interval reporting data to ADHS regarding opioid-related events (ADHS, 2017). Required reporting also includes data related to naloxone dispensed by a pharmacist or given to individuals who may be experiencing opioid overdose (ADHS, 2017). Collecting this data will provide local health officials, care providers, and community members with a better understanding of the impact of the opioid epidemic on local hospitals, emergency services, and communities, as well as aiding in refining targeted strategies to reduce the epidemic burden (ADHS, 2017).

Opioid Consent Program

Thus, St. Joseph's Hospital and Medical Center commenced its *Opioid Consent* initiative. This program was conceived by an interdisciplinary team of clinicians, including physicians, nurse managers, and pharmacists. Conceptually, every patient prescribed an opioid will receive education regarding the risks and benefits of opioid use, enabling each patient to make an informed decision by giving or withholding their consent to receive an opioid based on the education they received. This initiative includes both inpatient orders for opioids and opioid prescriptions written at discharge (outpatient). The consenting process is to occur for each inpatient receiving opioids with the exception of end of life/hospice care, pain associated with active malignancy, surgical or other invasive procedure, changing the type or dose of a narcotic, an opioid regimen three days or less, and neonatal abstinence syndrome. For patients at discharge who receive a prescription for an opioid, the exception for consent is made for: pain associated with active malignancy, hospice, and patients previously consented during their inpatient status. This program evaluation will focus on opioid prescriptions written at discharge.

The consenting workflow begins once a provider orders an opioid; prescribers are now required to query the Arizona Prescription Monitoring Program (AZ PMP) each time an opioid is ordered. Daily generated reports indicating which inpatients meet the criteria for opioid consenting are disseminated to each unit's nursing staff. The nurse is then tasked with notifying any rounding provider (ideally the provider managing pain) of the patient's need for opioid education and consent. In turn, the provider will include a discussion regarding opioid use with the patient as a part of their rounding and patient examination. Once this conversation is completed, the provider will place an order in the EHR for *Consent for Opioids*, which triggers a

corresponding task item for the patient's nurse and signifies the completion of opioid patient education. The nurse then proceeds with a physical copy of the opioid consent document (Figure 1) for the patient to sign, verifying that education was provided and the patient consents to receive an opioid.

The actual consent document models that of the ADHS recommended American Academy of Pain Medicine (n.d.); highlighting potential risks, alternatives, and intended use of opioids in easy to understand language for patients, as well as ensuring patients were given the opportunity for questioning and discussion with the prescribing provider. Extensive education regarding the need and intent of the opioid consent program was provided to clinicians and nursing personnel through multiple routes, including live presentations, email, posted flyers, and individual unit-based daily huddle briefings for a one-week duration, culminating with program initiation on December 2, 2019.

Intended Evaluation

Project Purpose

The purpose of this program evaluation was to explore the impact of St. Joseph's opioid consent initiative on documented Narcan use and provider prescribing patterns of opioids at discharge in accordance with recommendations and strategies set forth by the CDC and ADHS in efforts to increase opioid patient safety. Strategies that not only provide adequate pain control for patients but also coincide with safety and optimal prescribing patterns of current opioid efficacy standards are warranted immediately (Calcaterra et al., 2017). The opioid consent program is currently ongoing; therefore, resultant data and insights drawn from this formative evaluation

will aid in future efforts for successful adoption and refinement of the opioid consent program and overall patient safety.

Project Question

How does the incorporation of an opioid consent program (I) compared with previous practices, (C) impact Narcan use and opioid prescriptive trends (O) in the acute care setting (P)?

Project Objectives

This evaluation's primary objective is to determine the impact, if any, of the opioid consent program in establishing safe patient care practices pertaining to facilitating patient access to opioids upon discharge from the acute patient care setting. The incentive behind this program is that it is collaborative by design and facilitates patient autonomy and participation in medical decision-making, purporting better outcomes and care provision for all those involved, an evidence-based recommendation of the Centers for Medicare and Medicaid Services (CMS) (2017). Additionally, the legislative ruling, which this project originates, was designed to improve the health and safety of patients receiving opioid medications as a facet of their therapeutic regimen (ADHS, 2016).

Aim 1: Explore the reported use of Narcan for oversedation reversal at St. Joseph's Hospital and Medical Center.

Aim 2: Describe changes in the patterns of safe prescriptive opioid

Figure 1

Dignity Health Opioid Consent

CONSENT FOR OPIOIDS

My provider has informed me that I need, or may need, opioids, in the interest of my health and proper medical care.

My provider has explained to me the nature, purpose and possible consequences of the opioids, as well as significant risks involved, possible complications of and alternatives to opioids and possible options of obtaining other pain medications. I understand that opioids involve some risks to the patient even though precautions are taken. I also understand that despite the exercise of due care, opioids, and concurrent use of an opioid and benzodiazepine or another sedative-hypnotic medication may result in a dependence.

- i. The alternatives to opioids, including the risks and consequences of not receiving opioids, have been explained to me.
- ii. I have had the opportunity to discuss this matter with my provider, including options, and to ask questions.
- iii. I consent to opioids as ordered by my provider(s) during my hospitalization and/or at discharge.

Provider Name: _____

Patient Signature: _____ Date: _____
(patient/parent/legally authorized representative)

If signed by other than patient, indicate name and relationship: _____

Witness: _____ Name: _____
(Signature) (Print Name)

Date: _____

Interpreter: _____ Name: _____
(Signature) (Print Name)

Date: _____



CONSENT FOR OPIOIDS



CONSENT

X-MR-6102 (12/19)

Patient Label

Managing Your Pain

At Dignity Health, we are dedicated to providing for your comfort during your hospital stay. By managing your pain, you'll help improve your healing by utilizing specific medication(s) and alternatives, such as ice/ heat, therapies, to improve your pain. When using medications, you should take the smallest amount for the shortest time possible.

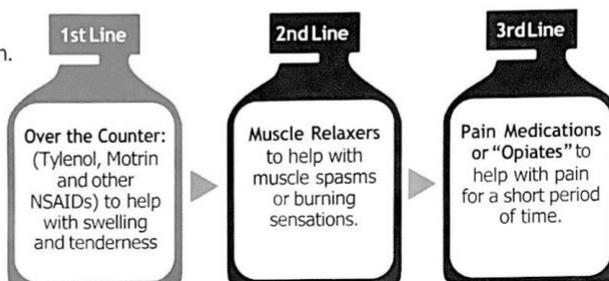


Treating Your Pain

There are several ways to treat your pain. The most common way is with medications.

Ask your nurse what medications have been ordered for pain and how they will be given. Some pain medications are given on a regular schedule and others are given as needed, when you ask for them.

Medications include:



Alternative Pain Relieving Measures: ice, heat, physical therapy, relaxation techniques, calm music, and position changes.

Risks/ Benefits

Like all medications, the opiate family comes with risks as well as benefits. The benefit of opiates is to control acute and chronic pain. Sometimes you may experience side effects from medications, which may include:

- Itching
- Constipation
- Nausea
- Dry mouth
- Sleepiness

More serious complications can include:

- Confusion
- Decrease breathing
- Low Blood Pressure
- Death (rare)

Non-opioid pain medicine should be used to help reduce the amount of opiate medication needed.

New Arizona Legislature

In January 2018, the Arizona legislature passed and the governor signed into law changes in how opioids, also known as pain medications, can be prescribed in Arizona. This new legislation covers all types of opioids including pills, patches, and liquids that could be prescribed at discharge.

This new law has limits on both how much and how long patients can receive any medication in the opioid family of pain medications.

If you have not received and filled an opioid prescription in the last 60 days, Arizona law considers you new to opioids. This means that when you leave the hospital, if you did not have a surgical procedure, you can only receive a maximum of 5 days of opioid medications. If you did have a surgical procedure, the maximum days of opioid prescription you can receive is 14 days. If you are new to opioids, Arizona law also limits the amount that can be prescribed to use per day. This limit varies by type of opioid and strength.

If you have any questions or concerns about this information, please talk to your provider. Thank you

Theoretical Framework

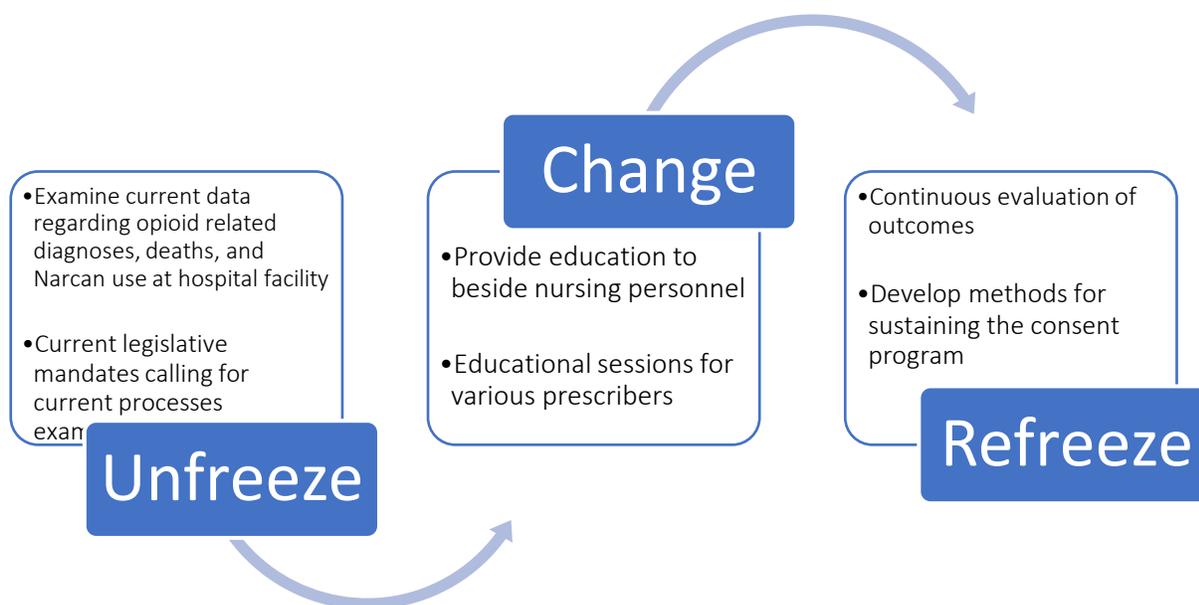
Although striking in its simplicity, Kurt Lewin's *Change Theory* is widely regarded as foundational to the science of change management (Cummings, Bridgman, & Brown, 2016). It is believed that this model first emerged immediately prior to Lewin's own death in 1947, and garnered popularity shortly thereafter (Cummings, Bridgman, & Brown, 2016). Critics and proponents of Lewin commonly assert that his change theory is most accurately portrayed and successfully employed as an interrelated facet of his other notable theoretical contributions: field theory, group dynamics, and action research (Batras, Duff, & Smith, 2016). Most closely aligned with change theory is the work of action research and its call for group collaborations over individuals and selection of the most appropriate change solution from the assessed possibilities (Batras, Duff, & Smith, 2016). At this, Lewin makes note that even the best-postulated solutions for change may be short-lived unless enacted upon with motivation and in-depth understanding behind the need for change, and thus his change theory emerged (Lewin, 1947).

Change theory can be described as change in three steps: unfreezing, change, and refreezing (Lewin, 1947). Unfreezing involves an introspective assessment of one's current beliefs, values, or behaviors followed by a subsequent upheaval as a catalyst or motivation for accepting change as necessary (Lewin, 1947). The change phase involves the implementation and trial of the desired change, as well as the promotion of supportive forces while simultaneously removing and reducing barriers (Batras, Duff, & Smith, 2016). Refreezing implies a realignment of practices, beliefs, and culture that supports the continuation of the change, ensuring its permanency (Batras, Duff, & Smith, 2016).

Regarding this program evaluation, the utilization of Lewin's change theory is both pragmatic and readily feasible. The aspects of the unfreezing phase include both state and federal legislative mandates for changes to prescribing practices and reviewing existing data trends regarding current Narcan use and opioid prescribing. The change phase involves providing education to prescribers and nursing personnel on the necessity and use of the opioid consent and incorporating the consenting process into current patient care workflows. Continuous evaluation of the related outcomes as well as streamlining and cementing the incorporation of the consenting program into care provision practices demonstrates the refreezing phase (Figure 2).

Figure 2

Kurt Lewin's Change Theory Adopted for Opioid Consent Program



Literature Synthesis

Evidence Search

A literature search was conducted for opioid prescribing and consenting. The CINAHL and PubMed databases were searched using the initial search-string: “opioid [MeSH]” AND “epidemic” AND “narcotic contract [MeSH].” This phrasing resulted in 244 various journal articles, expert opinions, and studies from 1988 through 2020. The results were refined to 228 works by the use of *full text* and *English language* filters. The time period was updated only to include articles published after 2015, leaving 146 items. Lastly, only peer-reviewed articles were selected, yielding 51 articles that underwent detailed review by the author, resulting in the final 19 included articles. The following themes were identified: criticisms of narcotic contracts, the need for Narcan as a proxy for oversedation, and pressures to prescribe.

Comprehensive Appraisal of Evidence

Criticisms of narcotics contracts. A scarcity exists of literary evidence and related studies regarding inpatient opioid consents; however, “narcotic contracts” or “opioid use agreements” are commonplace in the outpatient, chronic pain setting. Briefly, a narcotic contract is a treatment agreement between a patient and clinician that sets expectations for patient use of these high-risk medications (Overcarsh et al., 2019; Rager & Schwartz, 2017; Tobin et al., 2016). Commonly, these types of agreements include: informing the patient of the risk for opioid tolerance and physiologic dependence, requiring a singular prescribing doctor and dispensing pharmacy, stating lost or stolen medication will not be replaced, and detailing assessments for compliance, as in urine testing and pill counts (Overcarsh et al., 2019; Rager & Schwartz, 2017). By signing such agreements, patients acknowledge that if the contract terms are violated, they

may no longer receive controlled medications (Overcarsh et al., 2019; Rager & Schwartz, 2017; Tobin et al., 2016). Despite their widespread popularity and support from numerous national organizations aiming to mitigate opioid diversion and misuse, critics of contracts claim that these agreements encroach upon patient rights with unjust surveillance, stigmatize the patient, and border unethical (Overcarsh et al., 2019; Rager & Schwartz, 2017; Tobin et al., 2016). These agreements are thought to be detrimental to patients with their use of pejorative and coercive language and non-adherence to health literacy print material guidelines (Tobin et al., 2016).

Furthermore, medical ethicists have argued that agreements may violate principles of autonomy and reinforce an outdated and harmful, paternalistic approach to patient care by failing to share decisions (Chapman et al., 2017; Tobin et al., 2016). With this, the literature provides only scant amounts of evidence that endorse patients signing a narcotic contract decreases the likelihood of patient misuse and abuse; however, changing patient behavior is not the contract's purpose (Chapman et al., 2017; Rager & Schwartz, 2017). It is believed that much of the criticism of narcotic contracts is rooted in a misunderstanding of the document's intent and ethical standing (Rager & Schwartz, 2017). The key objectives of such agreements are to serve as a disclosure of the aforementioned prescribing policies and drug-related information, improve adherence, and mitigate risk (Tobin et al., 2016). These agreements are not intended to be indicative of acceptance of supervised medication use.

Additionally, the ethics of public health, namely addressing the widespread and well-documented abuse and misuse of opioid pain medications, serve as justification for patient monitoring practices and prescribed opioids that these agreements disclose (Tobin et al., 2016). There is a need for a nuanced approach that suggests controlled-substance agreements be

universally applied, use deliberate and understandable language, be framed in terms of safety, and be implemented according to the principles of shared decision-making (Tobin et al., 2016). This type of collaborative, safety-focused approach provides patients with important insights and is positively correlated with improved patient recovery, outcomes, satisfaction, and knowledge (Glowacki, 2015).

The need for narcan as a proxy for oversedation. In order to fully understand and address the opioid pandemic, namely adverse events such as overdose/oversedation, it is imperative to differentiate overdose occurring outside of hospitals requiring subsequent care at a hospital from overdose/oversedation, which occurs within health care facilities following opioid administration by licensed personnel. This difference equates to the variable causations and subsequent inferences needed to accurately and adequately address the multifaceted nature of the opioid pandemic (Green et al., 2019; Meidenberg et al., 2017). This notion is especially true regarding the intricacies of providing adequate pain control upon discharge while tasked with balancing the poor outcomes of uncontrolled pain against the consequences of opioid use, including oversedation (Green et al., 2019). Patient harm due to opioid-induced oversedation or respiratory depression is a nationwide issue involving all opioid preparations (Meidenberg et al., 2017). Estimates of life-threatening respiratory depression are imprecise and vary according to the population being studied, route of administration, and patients' risk factors (Meidenberg et al., 2017; Soto & Yaldou, 2015). In the inpatient environment, polypharmacy is considered one of the top reasons for oversedation (Khan et al., 2020).

Additionally, perioperative opioid use is associated with an increased risk for respiratory depression (Khelemsky et al., 2015; Meidenberg et al., 2017). A frequency of 0.5% is commonly

cited, but this apparently low percentage translates into a high burden of serious events, considering the 51 million surgeries performed each year in the US and the increased rate of opioid use in nonsurgical inpatients (Meidenberg et al., 2017; Soto & Yaldou, 2015). In a study of 1.14 million admissions, 51% of nonsurgical patients received opioids, with nearly a quarter of those patients receiving more than 100 MME daily (Brant et al., 2018; Calcaterra et al., 2017; Guy et al., 2017). Another study found that when pain was treated based purely on a numeric scale serving as the “fifth vital sign,” the incidence of adverse events related to opioids increased by greater than 100% (Soto & Yaldou, 2015). Furthermore, data from the American College of Surgeons Committee on Trauma revealed that the incidence of inpatient death related to opioid overuse similarly increased following the implementation of “fifth vital sign” recommendations by the originators of the concept, the American Pain Society, in an effort to promote awareness of pain treatment among health care professional (Soto & Yaldou, 2015).

Although respiratory depression is less common than sedation, it is the most serious of opioid-related complications and is associated with significant mortality (Brant et al., 2018). Inpatient oversedation independent of other variables can be a challenging clinical scenario to surveil and glean from electronic patient documentation; however, Narcan administration is a useful surrogate indicator of oversedation because of its routine use for opioid reversal in suspected overdoses and its feasibility in data tracking amongst the EHR (Brant et al., 2018; Meidenberg et al., 2017; Soto & Yaldou, 2015). Conclusions drawn from reviewing data for Narcan use as a proxy for opioid oversedation can be emblematic of the role healthcare providers play in potentiating the opioid epidemic, as well as highlight areas for improvement. As is the

impetus behind all healthcare provision, acknowledging the patient and the provider's shared influence on health outcomes, opioid adverse events are no exception.

Pressures to prescribe. As previously mentioned, pain management has played a significant role in measuring care quality, enhancing patient experiences, and subsequent reimbursements (Centers for Medicare and Medicaid Services [CMS], 2017; Glauser & Money, 2018; Pozek, De Ruyter, & Khan, 2018). In brief, the higher patients rank their satisfaction with pain control while receiving care on the Hospital Consumer Assessment of Health Providers and Systems (HCAHPS) survey, the more readily reimbursements are disbursed to clinicians and health systems. When patient satisfaction metrics are tied to pain relief efforts, inevitably questions regarding opiate therapy, once regarded as the “gold standard” for pain relief, and possible overprescribing will come into play (Glauser & Money, 2018; Pozek et al., 2018). A survey of ED physicians revealed that 71% of participants perceived pressure to prescribe opioids for pain control in order to avoid criticism and collectively expressed concerns regarding the impetus for patient satisfaction scoring by reimbursement officials in evaluating patient care (Calcaterra et al., 2017; ONDCP, 2017). This all changed in 2017 when the Centers for Medicare and Medicaid Services (CMS) (2017) stated it would no longer provide hospital reimbursement based upon consumer perceived pain management results in an effort to deter overprescribing of opioids to boost survey results.

Current CMS guidelines for pain management promote patient-inclusive goal setting for pain control, non-pharmacological and multimodal approaches, with opioid use as a last resort (US Department of Health and Human Services [HHS], 2018). The consensus amongst the literature remains that it is a provider's duty is to alleviate pain responsibly, and with a

multidisciplinary approach so that the most comprehensive care is provided, risk of patient harm minimized, and provider liability decreased (Calcaterra et al., 2017; Harbaugh & Suwanabol, 2019; HHS, 2018; ONDCP, 2017).

Strengths of Evidence

Due in part to the nondiscriminatory nature of the opioid epidemic affecting a myriad of individuals, increasing interest and transparency surrounds this subject matter. This increased interest has been translated into notable amounts of government funding and support, enabling more robust research regarding opioid safety and risk mitigation to be conducted (CDC, n.d.; Glauser & Money, 2018; Pozek, De Ruyter, & Khan, 2018). Because of increased surveillance efforts and governmental support, future studies will have a plethora of collected data available for use, resulting in larger, more robust studies (Rager & Schwartz, 2017; Tobin et al., 2016).

Weaknesses of Evidence

Studies regarding the effectiveness of various opioid prescribing management approaches that mitigate risk (i.e., risk assessment tools, opioid prescribing agreements, and use of prescription drug monitoring programs) are considered low in quality and commonly difficult to apply to the broader population outside of the study setting due to the complex nature of conducting such studies (CDC, n.d.; CDC, 2019; Chapman et al., 2017; NIH, 2020; Khelemsky et al., 2015). Amongst the existing literature, there is also a lack of supporting evidence regarding the best content to be included in patient-provider treatment agreements (Chapman et al., 2017; Khelemsky et al., 2015; NIH, 2020). Further studies demonstrating the effects of opioid agreements on patient care and establishing the incidence of diversion and opioid-related adverse outcomes may aid in substantiating their use more commonly (Overcarsh et al., 2019;

Rager & Schwartz, 2017; Tobin et al., 2016). Additionally, only a few large-scale studies exist regarding the specifics surrounding naloxone recipients in the inpatient setting (Green et al., 2019; Khelemsky et al., 2015).

Gaps and Limitations

A recurring challenge for providing patients with the safest, most effective pain treatment lies in the complexities of translating research findings into clinical practice (Glowacki, 2015). These complexities include applying an evidence-based approach to current practices and integrating interdisciplinary collaborative approaches (Glowacki, 2015). The literature also indicates a persistent gap between comprehension of the pathology of pain and subsequent treatment recommendations (Calcaterra et al., 2017; Glowacki, 2015; Guy et al., 2017). Additional limitations include the constraints of chart auditing tools and technology. Often times current EHR software struggles with extracting data related to complex clinical scenarios such as opioid reversal and oversedation to readily yield corresponding, useful data (Glowacki, 2015; Meisenberg et al., 2017). The expansive research chronicling the nation's journey through mitigating the opioid crisis undoubtedly demonstrates that significant changes and improvements are feasible; however, the need for such innovations persists (Guy et al., 2017).

METHODS

Setting

This project took place at St. Joseph's Hospital and Medical Center, a 595-bed, Level 1 Trauma Center, located in the metropolitan city center of Phoenix, Arizona. St. Joseph's is a faith-based, not-for-profit, academic facility. For more than a century, St. Joseph's has served as a hub for medical education, research innovation, and is recognized internationally for its

neurology and neurosurgical care (Dignity Health, n.d.). This hospital is also a part of the broader healthcare delivery organization, Dignity Health, one of the largest healthcare systems in the western US, boasting more than 40 hospitals in Arizona, California, and Nevada (Dignity Health, n.d.).

The city of Phoenix, located within Maricopa County, serves as the state capital of Arizona, is situated amongst the Sonoran Desert landscape covering 517 square miles, and houses a population of approximately 1.68 million people (US Census Bureau, 2019). Phoenix consistently ranks amongst the top five most populous US cities annually (US Census Bureau, 2016). The majority of residents are white, 72.3%, with 43% non-Hispanic whites, 42.6% Hispanic, 6.9% Black/African American, 3.8 % Two or more races, 3.7 % Asian, and 2.1% American Indian/Alaskan native. The median age is 33.5 years, and the median household income from 2014- 2018 was \$54, 765, with approximately 19.4 % of people in poverty (US Census Bureau, 2019). Arizona is also home to 22 sovereign American Indian tribes whose historical influences remain significant on the present-day culture of Phoenix; most notably from the neighboring Ak-Chin, Gila River, Salt River, and Tohono O’Odham tribes (Arizona Office of Tourism, 2020).

Project Design

This formative program evaluation was descriptive by design. Pre and post outcome measurements were used to determine whether there was a correlation between the program’s intent and resultant data. More specifically, a comparison of the data regarding Narcan administration and opioid prescriptions at discharge from the periods six months before and six months after initiation of the opioid consenting program was used to determine whether

summative reductions of these two variables correlated with the consent program and its intent to increase safety regarding opioid usage.

Model for Evaluation

Effective program evaluations have the ability to systematically improve and substantiate healthcare innovation in a meaningful and purposeful way (CDC, 1999). The CDC's *Framework for Program Evaluation* (1999) guided the process of this evaluative project. This framework has been regarded as a practical, non-prescriptive tool, developed for summarizing and organizing the essential steps in successful program evaluation (CDC, 1999). This model centers upon four standards for evaluation that serve as guides as an individual works through each step of the framework and is depicted in Figure 3 (CDC, 1999).

- Utility
 - Who benefits from the evaluation results? Will this evaluation provide relevant and timely information?
- Feasibility
 - Are the planned evaluation activities realistic given the time and resources available?
- Proprietary
 - Are the welfare and individual rights of those involved protected? Are those most directly affected by the program engaged?
- Accuracy
 - Ensuring evaluation results are valid, reliable, and pertain to the needs of those using and impacted by the results

Figure 3

CDC Framework for Program Evaluation in Public Health



Accordingly, the six interconnected, nonlinear steps of completing an evaluation (CDC, 1999) encompass the standards for effective evaluation:

- Engage Stakeholders
 - Ascertain input and considerations of those involved or affected by the program and primary users of the evaluation
- Describe the Program
 - Determine needs, intended effects, resources, context, and activities

- Focus the Evaluation Design
 - Focusing the intent of evaluation and articulating what necessary steps will be needed
- Gather Credible Evidence
 - Collection of information that is comprehensively reflective of the program, in order to be perceived as credible and worthwhile to stakeholders and users
- Justify Conclusions
 - Includes analysis, synthesis, and interpretation of results followed by recommendations
- Ensure Use and Share Lessons Learned
 - Soliciting feedback, refining design, performing follow up and facilitating the dissemination

The evaluative process begins with engaging stakeholders in order to ascertain input and considerations of those involved or affected by the program, as well as the primary users of the program. Stakeholders for this project included providers at this institution with prescriptive authority such as physicians, nurse practitioners, physician assistants, fellows, residents, and medical students. These individuals play a key role by prescribing opioid medications in both the acute setting and at discharge, utilizing clinical judgement in assessing individual patient risks for abuse of opioids. Pharmaceutical staff serve as resources for personnel within the acute care setting and document and provide records pertaining to Narcan use and opioid prescriptive trends. Nursing personnel are critical to the implementation and completion of the opioid consenting process and also facilitate confirmation of the provision of patient education. This evaluation project also included engaging key members involved in developing the opioid consent program initially. These stakeholders included the physicians, nurse managers, and

pharmacists who were members of the collaborative, interdisciplinary team that conceived the project.

The next evaluative phase, *describing the program*, was accomplished by discussions with stakeholders regarding which elements of the program would be appropriate to evaluate, as well as the justification behind the chosen elements. The choice of Narcan use and opioid availability based upon discharge prescribing patterns are representative of the intended safer opioid usage practices. The third phase of evaluation, *focusing the evaluation design*, coincides with the selection of an evaluation's focus on either program processes or outcomes. For this project, the focus was on outcomes, to determine whether a reduction in corresponding data points of both Narcan and prescribing-related outcomes would indicate meeting the intended program's purpose of increasing safety. More specifically, Narcan use and opioid prescribing patterns were chosen because of these elements' readily available and measurable nature. A detailed depiction of the evaluation plan adopted from the CDC's *Logic Model* (2011) is included in Table 1 below.

Table 1*Logic Model for Opioid Consenting Program*

Inputs	Activities	Outputs	Short Term Outcomes	Intermediate Outcomes	Long Term Outcomes
<ul style="list-style-type: none"> • Multidisciplinary team of clinicians to contribute a variety of perspectives • Abiding by legislative mandates and incorporation of practice standards and guidelines from governing bodies and accrediting orgs. • Current data regarding St. Joseph's opioid prescriptions and Narcan administrations, as well as patient outcomes and adverse events 	<ul style="list-style-type: none"> • Educational presentations, email blasts, and electronic and paper materials for providers, APPs, residents, and nurses regarding the background, indications, and a stepwise opioid consent facilitation • Collaboration with informatics dept. for notification integration within the EHR 	<ul style="list-style-type: none"> • Opioid consent incorporated into inpatient nursing and provider workflows customized to each surgical patient transferred to ICU • Opioid consent completed on every patient that meets inclusion criterion • Daily patient safety huddles on each inpatient unit for nursing staff identifying patients meeting consent criterion 	<ul style="list-style-type: none"> • Reduced number of Narcan dose administrations • Reduced number of opioid prescriptions • Compliance in the use of the opioid consents for each patient meeting inclusion criterion 	<ul style="list-style-type: none"> • Streamlined, exclusively electronic consenting process • Consenting program adopted by all AZ service area facilities 	<ul style="list-style-type: none"> • Improved patient safety • Reduced adverse events related to opioids, i.e. oversedation • Disseminated use of the opioid consent to all members of the Hospital Association of Arizona

Adapted from the CDC Logic Model (2011). In Introduction to Program Evaluation for Public Health Programs: A Self-Study Guide (p.21). Georgia: U.S. Department of Health and Human Services center for Disease Control and Prevention.

Aligning with the fourth phase, *gathering credible evidence*, Narcan administration is currently accounted for by the facility's Medication Utilization and Patient Safety (MUPS) Manager, a key stakeholder, on a recurring basis as a part of a duty to report this data to the ADHS. The data collection includes electronically auditing inpatient EHRs via a query for Narcan use, resulting in numerical values with associated documented reasons for the use of Narcan. In the same manner, data were extracted by the hospital's MUPS manager as a numerical value, with no patient identifiers, from the electronic health records of all patients who meet consent program inclusion criterion via a system query regarding prescription opioids upon discharge from the time period six months immediately prior to the opioid consent implementation, June 2019 to December 2019. In turn, the same EHR query was completed for the six-month period immediately following consent implementation, December 2019 to June 2020.

Once collected, the data were arranged and depicted as a summative table, representative of each variable with its corresponding documented reason for use, and time period. Subsequent comparisons of correlating data points from each six-month pre and post period were performed in order to extrapolate resultant variances to clinical implications. According to Wilson et al. (2020), surveilling substance use-related data such as this as a means for trending emerging threats and barriers, enhancing connections to treatments and a multifaceted response approach are essential to sustain and expedite declines in opioid-related deaths.

The fifth step in the evaluation, *justify conclusions*, includes analyzing the collected information, interpreting, and drawing conclusions from the data (CDC, 1999). Statistical analysis included rudimentary tabulations of variable frequencies, totals, percentages, and central

tendency measures for each respective time period. Additional inferential analysis computations were completed to determine the presence of statistically significant differences between the reported variables from the pre and post time periods. A designated alpha level of .05 was employed. The analysis was completed using Microsoft Excel software. According to the framework, *ensuring use and sharing lessons learned*, is the final phase of evaluative efforts (CDC, 1999). In addition to the aforementioned data collection currently completed by the MUPS manager, a Patient Safety and Performance Improvement meeting is held quarterly and serves as a mechanism for continual reassessment. Much of the same data collected for this evaluation is also presented at these meetings, serving as depictions of ongoing trends and providing supporting evidence for continued improvement needs and further program refinement. In regards to dissemination, as previously stated, the evaluation site, St. Joseph's Medical Center, is a part of the larger care delivery system, Dignity Health, which possesses numerous other hospitals and facilities across Arizona and the Western US. As implementation efforts of the opioid consent program continue for this specific site, the interconnected Dignity Health care system has this advantage for easily facilitated dissemination of the opioid program at these additional campuses. By doing so, even more patients of varying and distant populations have the opportunity to benefit from any resultant benefits of the opioid consent program.

Ethical Considerations

Prior to data collection, permission to proceed was obtained from the University of Arizona and the St. Joseph's Hospital and Medical Center IRB review boards. Determination of Human Research approval was obtained before the program evaluation as well. Only the primary investigator had access to all related data files. At the conclusion of this program evaluation

project, the University of Arizona, Office of Research and Scholarship are storing collected data for six years.

RESULTS

Outcomes

The following tables show the frequencies for each discharge prescription opioid drug ($N = 11$) by month in the respective pre and post implementation periods (Tables 2 and 3).

Descriptive statistics were completed for the overall pre and post implementation periods regarding opioid discharge prescriptions. These values are detailed in Table 4.

Table 2

Pre-Implementation Period Opioid Prescription Frequencies

	<i>Jun 19</i>	<i>Jul 19</i>	<i>Aug 20</i>	<i>Sep 19</i>	<i>Oct 19</i>	<i>Nov 19</i>	<i>Pre- Implementation Period Total</i>
<i>Acetaminophen/Codeine</i>	26	23	35	39	35	22	180
<i>Acetaminophen/Hydrocodone</i>	329	371	273	282	309	282	1846
<i>Acetaminophen/Oxycodone</i>	470	407	508	415	396	383	2579
<i>Fentanyl</i>	8	4	7	10	7	21	57
<i>Hydrocodone</i>	0	1	2	2	0	1	6
<i>Hydromorphone</i>	29	19	34	21	21	27	151
<i>Meperidine</i>	0	0	0	0	0	0	0
<i>Methadone</i>	3	4	8	2	5	3	25
<i>Morphine</i>	49	47	53	47	56	40	292
<i>Oxycodone</i>	605	770	809	689	736	710	4319
<i>Tramadol</i>	341	310	365	345	320	295	1976
<i>Total</i>	1860	1956	2094	1852	1885	1784	11431

Table 3*Post-Implementation Period Opioid Prescription Frequencies*

	<i>Jan 20</i>	<i>Feb 20</i>	<i>Mar 20</i>	<i>Apr 20</i>	<i>May 20</i>	<i>Jun 20</i>	<i>Post- Implementation Period Total</i>
<i>Acetaminophen/Codeine</i>	12	13	5	10	13	12	65
<i>Acetaminophen/Hydrocodone</i>	249	233	224	126	208	118	1158
<i>Acetaminophen/Oxycodone</i>	316	304	271	189	242	129	1451
<i>Fentanyl</i>	4	4	7	5	2	1	23
<i>Hydrocodone</i>	0	1	1	0	0	0	2
<i>Hydromorphone</i>	23	19	8	18	23	11	102
<i>Meperidine</i>	0	1	0	0	0	0	1
<i>Methadone</i>	4	1	1	3	4	1	14
<i>Morphine</i>	48	32	32	20	35	10	177
<i>Oxycodone</i>	667	727	669	406	585	307	3361
<i>Tramadol</i>	211	241	214	156	159	87	1068
<i>Total</i>	1534	1576	1432	933	1271	676	7422

Table 4*Descriptive Statistics of Prescription Opioids*

	<i>Median</i>	<i>Mean</i>	<i>SD</i>	<i>Range</i>
<i>Pre-period</i>	180	1039.18	1445.09	0 - 4319
<i>Post-period</i>	102	674.73	1045.09	1 - 3361

A Sign test was used for determining the presence of a statistically significant ($\alpha = 0.05$) difference between the pre- and post-implementation period data for prescription opioid quantities. In regards to prescribed opioids at discharge, the data from the pre-implementation period (*Median* = 180, *Mean* = 1039.18, *SD* = 1445.09) and post-implementation period (*Median* = 102, *Mean* = 674.73, *SD* = 1045.09) resulted in a statistically significant decrease in the number of prescribed opioids, $Z = 2.7136$, $p = .00666$, see Table 5 below.

Table 5*Inferential Statistics of Prescription Opioids*

<i>Prescription Opioid Frequencies</i>			<i>Sign Test Statistics</i>	
<i>Pre-Post</i>		<i>N</i>		<i>Pre-Post</i>
	Positive Differences ^a	10	<i>Z</i>	2.714
	Negative Differences ^b	1	<i>Sig. (2-tailed)</i>	.00666
	Ties ^c	0		
	Total	11		

a. Pre > Post
b. Pre < Post
c. Pre = Post

Frequency data regarding Narcan administrations by indicated use ($N = 2$) are depicted below as a part of Table 6. A Sign test was also used for determining the presence of a statistically significant difference in the number of Narcan administrations from the pre- and post-implementation periods. The difference from the pre-implementation period (Mean = 85, SD = 90.51) and post-implementation period (Mean = 96.5, SD = 105.36) was not statistically significant, $Z = 1.41421$, $p = .1573$, $\alpha = 0.05$ as detailed in Table 7 below.

Table 6*Pre/Post Period Frequencies of Narcan Administration*

		<i>Pre- Implementation</i>	<i>Post- Implementation</i>
<i>Uses</i>	<i>ED/Home</i>	149	171
	<i>Possible Over-sedation</i>	21	22
	<i>Total</i>	170	193

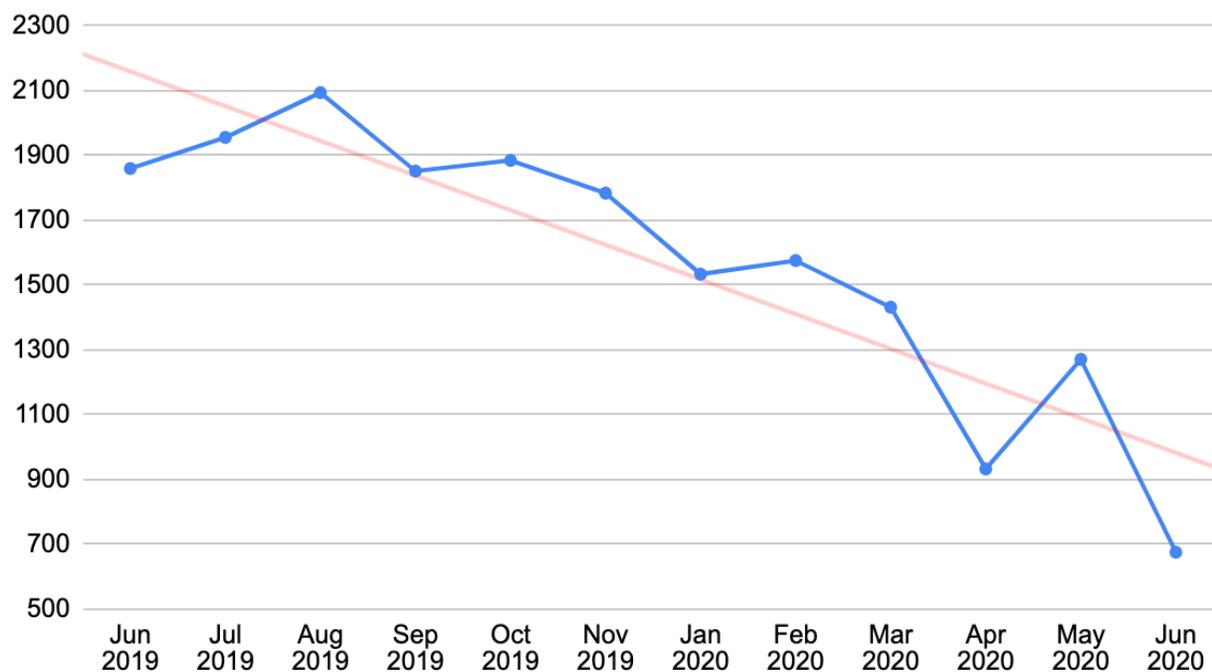
Table 7*Inferential Statistics of Narcan Use*

<i>Narcan Use Frequencies</i>			<i>Sign Test Statistics</i>	
		<i>N</i>		<i>Pre-Post</i>
<i>Pre-Post</i>	Positive Differences ^a	0	<i>Z</i>	1.414
	Negative Differences ^b	2	<i>Sig. (2-tailed)</i>	.1573
	Ties ^c	0		
	Total	2		

a. Pre > Post
b. Pre < Post
c. Pre = Post

DISCUSSION**Interpretation**

As illustrated below by Figure 4, the total number of opiate prescriptions at discharge decreased significantly from the pre-implementation to post-implementation period. This difference can be attributed to a multitude of factors, which will be discussed in detail further as a part of this project's limitations. Additionally, the variability in quantity of each opiate drug for both pre and post periods was substantially skewed (Table 2 & 3). The skewness of both the pre and post-implementation periods (1.39, 1.96 respectively) is outside of the commonly acceptable range of +/- 1 for normal distributions of data (Pett, 2015). Thus, the resultant data was interpreted by non-parametric means. The Sign test is a non-parametric test, which makes very few assumptions about the nature of the distributions of data being tested (Pett, 2015). This means that it has very general applicability, but may lack the statistical power of alternative tests, such as the Wilcoxon signed-rank test (Pett, 2015). Due to the small sample size of this data, a binomial distribution was warranted for inclusion in the non-parametric calculation for the Sign test as well (Pett, 2015).

Figure 4*Total of Monthly Opioids Prescribed Over Time*

It is also important to note that the number of Narcan administrations increased in the post-implementation period. This unanticipated increase in administrations, despite an overall reduction in the number of prescribed opioids, is a multifaceted observation. Regarding the category of Narcan with ED/home use indications; this category coincides with Narcan administrations that were documented as given by ED personnel with the patient having never received a narcotic as a part of their emergent treatment interventions. Therefore, this is indicative of scenarios that include an initial patient presentation with a possible diagnosis of overdose at home, prior to arrival in the ED.

Additionally, the same newly implemented legislation that prompted the inception of the opioid consent initiative also notably increased access and availability of Narcan for use at home

to individuals with an increased risk for adverse events secondary to their use of opioids. Furthermore, first responders, law enforcement, and medics alike all received extensive training and education regarding Narcan use under these legislative mandates in efforts to positively affect patient outcomes prior to an individual's arrival in the acute care setting. Consequently, the impact of these multiple legislative efforts and shortcomings of EHR documentation capabilities on the increase in data for Narcan use values is indeterminable as it pertains to this specific evaluation.

The number of Narcan administrations categorized for possible oversedation in the inpatient setting also increased in the post implementation period by one administration. This category coincides with the EHR documented resolution of suspected oversedation symptoms after the administration of Narcan. This observation increase is interesting in that it can be interpreted as a depiction of remaining knowledge gaps regarding safe opioid administrations by nursing personnel responsible for administering opioids within the acute setting. Of note, this opioid consent program was aimed at addressing the individual patient's knowledge of risks and benefits of opioid use rather than providing any education for clinicians and nursing staff administering the medications. Moreover, the patient education aspect of the opioid consent is to be provided by prescribing clinicians and then verified as 'completed' by nursing staff in the EHR. It would behoove stakeholders for this initiative to ensure that patient educators (i.e., clinicians) are in fact well informed and up to date on information regarding opioid safety, ensuring accurate information is being relayed to patients partaking in consenting. As this program continues, this notion could be addressed in the form of educational reference materials or brief, refresher lectures for health professionals involved in direct patient care.

Implications (Practice, Education, Research and Policy)

Based on these findings, the significant decrease in prescribed opiates in the post-consent program period can be considered as contributing to safer opioid use by reducing and limiting patient access to opiate prescriptions, and thus decreasing the risks associated with opioid use. This aligns with the intent of Arizona legislation and practice changes backing the creation of the opioid consent program, increasing safety with opioid use. Accordingly, this program evaluation of the preliminary incorporation of the opioid consent program may serve as a spur for further inquiry into effective ways to mitigate opiate-use related risks for patients while simultaneously empowering them through informed decision-making. By design, the opioid consent program was developed as a means to inform, educate, and empower patients in medical decision making by indirectly dissuading the use of opioids by presenting their risks, benefits, and non-opiate analgesic treatment alternatives. There is also the underlying benefit of reduced liability for healthcare facilities and clinicians by documenting a patient's consent to receive opioids after being made aware of their associated risks. With the aforementioned ballooning costs associated with opioid overdose care and treatment, diminishing these types of expenses for health systems remains a top priority and motivation for future study.

The opioid consent initiative did not significantly affect safety as it pertains to opioid oversedation reversal via Narcan use. Therefore, further research is warranted regarding the use of EHR auditing in order to glean useful and accurate data in order to assess and study oversedation in continued efforts to better serve those patients affected. Of note, this evaluation's data collection processes detailed the differences in quantities and frequencies of commonly used opiate drugs. This information is very useful in that it highlights potential areas for targeted

patient and prescriber education and intervention for future research. During its conception, an end goal for the opioid consent initiative was to have the consenting process become fully integrated into the EHR workflow for all participating clinicians and personnel. The challenges and successes demonstrated by this evaluation can serve as an impetus for future efforts towards facilitating this goal and refining current implementation practices. Lastly, while this program evaluation utilized a relatively small sample size, the results of larger, more robust inquiries on the use of opioid consents and related initiatives should be completed, contributing to the broader and pressing state and federal government efforts of curtailing opioid-related adverse patient events, namely death.

Limitations

Regarding data collection, the nature of the Narcan administration data that was abstracted from the EHR limited interpretation by not possessing capabilities to definitively document either patient-reported or EMS-reported use of opioids prior to arrival at the facility. The absence of this information limits the conclusions and interpretations that can be ascertained from this data. Considering the larger, all-encompassing problem of opioid abuse that is undeniably multi-faceted, this absence of detailed pre-hospital opioid use information greatly limits the feasibility and applicability towards solution finding in addressing the opioid epidemic. If such information was available for study, along with the related EHR hospital-setting data provided by this program evaluation, more insight could be garnered regarding opioid misuse in the community, prior to admission, further refining future mitigation intervention.

Furthermore, an additional insufficiency exists regarding the opioid prescription data collected. While the number of prescribed discharge opioids obviously decreased, it would be

advisable to consider this observation in conjunction with the total number of patient discharges during each pre- and post-implementation period. This additional information would lend itself to more clearly depicting a causal, rather than correlational, relationship for the opioid consent program and discharge prescriptions in light of the impact of COVID-19 detailed below.

Additionally, the decision was made to omit data from the entire month the opioid consent initiative was implemented, December 2019, from data analyses in order to ensure accuracy and a sense of equivalency in comparisons for the six months pre and post-implementation periods. This decision was largely due to constraints of the collected data in deciphering exact prescription ordering dates within the month of December either before or after the exact implementation date of December 3, 2019.

Impact of COVID-19

As depicted in Figure 4, the post-implementation period sums of prescribed opioids significantly decreased in comparison to the period prior to the opioid consent. However, it is important to note that during the post-implementation period, from approximately early March and continuing onward to the present day, the novel Corona virus pandemic ensued, with subsequent national quarantines, cancellation of elective procedures, reduced access to healthcare, etc. Each of these considerations possessed the potential to unfathomably impact our resultant data, namely by affecting the number of inpatients. The unknown magnitude and currently ongoing nature of this pandemic has the potential to remain a challenge for future evaluations and investigators to come. Nonetheless, the opioid prescription data did not have the adverse outcome of increasing in quantity during the post-implementation period. Therefore, it

would be worthwhile to continue the opioid consent program to further study and ascertain its impact on patient safety and mitigating opioid risks.

DNP Essentials Addressed

The completion of this program evaluation demonstrates the principle investigator's fulfillment of the following AACN's DNP essential competencies: scientific underpinnings, clinical scholarship and analytical methods for evidence-based practice, Information systems & patient care technology, health care policy for advocacy in health care, interprofessional collaboration for improving patient and population health, and clinical prevention and population health for improving the nation's health.

APPENDIX A:

DIGNITY HEALTH SITE APPROVAL/AUTHORIZATION LETTER



Research Compliance
350 West Thomas Road
Phoenix, Arizona 85013
Office: 602-406-9447
Fax: 602-406-7197

October 28, 2020
University of Arizona Institutional Review Board
c/o Office of Human Subjects
1618 E Helen St
Tucson, AZ 85721

Please note that Ms. Kalekia Adams, UA Doctor of Nursing Practice student, has permission of the St. Joseph's Hospital and Medical Center to conduct a quality improvement project at our facility for her project, "Opioid Consenting: A Novel Program to Address Opioid Safety."

Ms. Adams will conduct a program evaluation at St. Joseph's Hospital and Medical Center. She will review numerical data provided by the Medication Utilization and Patient Safety (MUPS) Manager regarding the quantity of Narcan administrations and opioid prescriptions. No patient specific information will be included.

Ms. Adams has agreed to provide to my office a copy of the University of Arizona Determination before she completes any program evaluation activities, including data collection. She will also provide evaluation results to the Patient Safety & Performance Improvement meeting via the MUPS manager.

Should you have any questions, please contact me at 602-406-9447 or via email to Julie.Barton@DignityHealth.org.

Sincerely,

A handwritten signature in black ink that reads "Julie Barton".

Julie Barton, BS, MHA
Research Integrity & Compliance Officer
Dignity Health Research Institute

APPENDIX B:
THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD APPROVAL
LETTER



Human Subjects
Protection Program

1618 E. Helen St.
P.O.Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
<http://rgw.arizona.edu/compliance/home>

Date: November 25, 2020

Principal Investigator: Kalekia Adams

Protocol Number: 2011244222

Protocol Title: "Opioid Consenting: A Novel Program to Address Opioid Safety"

Determination: Human Subjects Review not Required

Documents Reviewed Concurrently:

HSPP Forms/Correspondence: *Final IRB Determination w 11 23 edits.pdf*

Regulatory Determinations/Comments:

- Not Human Subjects Research as defined by 45 CFR 46.102(f): as presented, the activities described above do not meet the definition of research involving human subjects as cited in the regulations issued by the U.S. Department of Health and Human Services which state that "human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information."

The project listed above does not require oversight by the University of Arizona.

If the nature of the project changes, submit a new determination form to the Human Subjects Protection Program (HSPP) for reassessment. Changes include addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the study activity. Please contact the HSPP to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

APPENDIX C:
LITERATURE REVIEW GRID

Pub. Year Author's Last Name	Title of Publication	Type of Study	Main Outcomes or Findings	Support for and or link to project
2016 Brant et al.	Predictors of oversedation in hospitalized patients	Retrospective case-controlled study	<p>Demographic and clinical characteristics predictive of oversedation and potential opioid-induced respiratory depression (OIRD) in hospitalized patients.</p> <p>The identified risk factors for oversedation and potential OIRD in hospitalized patients can form the basis of quality-improvement initiatives to prevent oversedation through improved prescribing and patient monitoring.</p>	<p>Opioid-induced respiratory depression (OIRD) and oversedation are significant threats to hospitalized patients.</p> <p>Risk factors for OIRD and oversedation identified via regression modeling include female sex, comorbid renal disease, untreated sleep apnea, and certain opioid types and routes of administration.</p> <p>Organizations can develop quality-improvement tools to prevent oversedation and safeguard patients.</p>
2016 Calcaterra et al.	Opioid prescribing at hospital discharge contributes to chronic opioid use	Retrospective cohort study	<p>Main measure included chronic opioid use 1 year post discharge</p> <p>Chronic opioid use 1 year post discharge was more common among patients with opioid receipt (4.1 % versus 1.3 %, $p < 0.001$) compared to patients without opioid receipt. Opioid receipt was associated with increased odds of chronic opioid use (AOR=4.90, 95 % CI 3.22-7.45) and greater subsequent opioid refills (AOR=2.67, 95 % CI 2.29-3.13) 1 year post discharge compared to no opioid receipt</p>	<p>Opioid receipt at hospital discharge among opioid naïve patients increased future chronic opioid use. Physicians should inform patients of this risk prior to prescribing opioids at discharge.</p> <p>Further research is needed to develop interventions to assist physicians in making informed decisions about opioid prescribing at hospital discharge. Existing data already available in electronic medical records could alert physicians about patient-specific risk factors for opioid abuse or chronic use. Linking electronic medical records to prescription drug monitoring programs would allow physicians to verify opioid doses or other controlled substances patients are using.</p>

Pub. Year Author's Last Name	Title of Publication	Type of Study	Main Outcomes or Findings	Support for and or link to project
2017 Calcaterra et al.	The hospitalist perspective on opioid prescribing: A qualitative analysis	A qualitative study consisting of in-depth, semi-structured interviews	<p>Aimed at understanding physician's attitudes, beliefs and practices towards opioid prescribing during hospitalization and discharge.</p> <p>Although hospitalists felt confident in their ability to control acute pain using opioid medications, they perceived limited success and satisfaction when managing acute exacerbations of chronic pain with opioids.</p> <p>Hospitalists recounted negative sentinel events, which altered opioid prescribing practices in both the hospital setting and at the time of hospital discharge.</p> <p>Hospitalists described prescribing opioids as a pragmatic tool to facilitate hospital discharges or prevent readmissions. At times, this left them feeling conflicted about how this practice could impact the patient over the long term.</p>	<p>Strategies to provide adequate pain relief to hospitalized patients, which allow hospitalists to safely and optimally prescribe opioids while maintaining current standards of efficiency, are urgently needed.</p> <p>Physicians reported little opioid specific training during residency, and so opioid prescribing practices were shaped by the physicians' clinical experiences.</p> <p>Physicians used opioids as a tool to facilitate discharges and prevent readmissions; yet doing so sometimes left them feeling conflicted. On one hand, they felt pressure to maintain efficiency; on the other hand, they recognized it might not be in the patient's best interest to receive a higher than necessary quantity of opioids at discharge.</p>
2017 Chapman et al.	Opioid treatment agreements: helpful or hurtful?	Case Study	Contents, efficacy, and both advantages and disadvantages of Opioid Treatment Agreement use	<p>Although several groups recommend opioid treatment agreements (OTAs), there is little evidence to guide best use of these documents.</p> <p>The role of OTAs in limiting adverse outcomes, including the development of opioid use disorders in patients with chronic no cancer pain, is unclear.</p>

Pub. Year Author's Last Name	Title of Publication	Type of Study	Main Outcomes or Findings	Support for and or link to project
				<p>Medical ethicists have argued that OTAs may violate principles of autonomy and utilize a paternalistic approach to patient care.</p>
2015 Costello	Prescription opioid analgesics: Promoting patient safety with better patient education	Case Study	Risks and important aspects of opioid medication use in postoperative patients	<p>Given the alarming rates of opioid abuse and overdose deaths, it is imperative that patients be well informed about this class of medications before they leave the hospital.</p> <p>To ensure that patients with opioid medication prescriptions are discharged safely, they must be taught concerning benefits, adverse effects, and risks associated with opioids, including the possibility of tolerance, dependence, and addiction.</p> <p>It is imperative that patients fully understand the risks involved with the use of these medications. The nurse's role in patient education is invaluable to patients' understanding of the safe management of opioids.</p>
2018 Glauser & Money	Medical management of pain in the emergency setting without narcotics: Current status and future options	Literature review	This article presents current pharmacologic options regarding analgesia in the emergency setting, with some possible future options	- acute and emergency providers play a key role in furthering interventions to mitigate opioid safety because of their unique role in the gap between chronic use and acute issues

Pub. Year Author's Last Name	Title of Publication	Type of Study	Main Outcomes or Findings	Support for and or link to project
2015 Glowacki	Effective pain management and improvements in patients' outcomes and satisfaction.	Peer reviewed journal article	<p>-Effective management of acute pain results in improved patient outcomes and increased patient satisfaction. Although research and advanced treatments in improved practice protocols have documented progressive improvements in management of acute and postoperative pain, little awareness of the effectiveness of best practices persists. – Improved interventions can enhance patients' attitudes to and perceptions of pain. What a patient believes and understands about pain is critical in influencing the patient's reaction to the pain therapy provided.</p> <p>-Use of interdisciplinary pain teams can lead to improvements in patients' pain management, pain education, outcomes, and satisfaction.</p>	<p>- supports the notion of a gap/need persisting in the realm of interventions for safer opioid practices</p> <p>- demonstrates the complexities of adequate pain management, including risks of under and over prescribing of analgesics</p>
2018 Green et al.	Identifying and classifying opioid-related overdoses: a validation study	Validation study	This study aimed to develop and validate algorithms to identify and classify opioid overdoses using claims and other coded data, and clinical text extracted from the EHR using natural language processing	Demonstrates the complexities and necessity of the surrogate use of Narcan use a means for opioid overdosing auditing of electronic health records.
2017 Guy et al.	Vital signs: Changes in opioid prescribing in the united states, 2006-2015	Governmental Agency Data Report	CDC analyzed retail prescription data from QuintilesIMS to assess opioid prescribing in the United States from 2006 to 2015, including rates, amounts, dosages, and durations prescribed. CDC examined county-level prescribing patterns in 2010 and 2015.	<p>Despite reductions in opioid prescribing in some parts of the country, the amount of opioids prescribed remains high relative to 1999 levels and varies substantially at the county-level.</p> <p>Given associations between opioid prescribing, opioid use disorder, and overdose</p>

Pub. Year Author's Last Name	Title of Publication	Type of Study	Main Outcomes or Findings	Support for and or link to project
			<p>The number of opioids prescribed in the United States peaked at 782 morphine milligram equivalents (MME) per capita in 2010 and then decreased to 640 MME per capita in 2015. Despite significant decreases, the number of opioids prescribed in 2015 remained approximately three times as high as in 1999 and varied substantially across the country. County-level factors associated with higher amounts of prescribed opioids include a larger percentage of non-Hispanic whites; a higher prevalence of diabetes and arthritis; metropolitan status (i.e., town/city; nonmetro); and higher unemployment and Medicaid enrollment.</p>	<p>rates, health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines, such as <i>CDC's Guideline for Prescribing Opioids for Chronic Pain</i>, and consider nonopioid therapy for chronic pain treatment.</p> <p>The substantial variation in opioid prescribing observed at the county-level suggests inconsistent practice patterns and a lack of consensus about appropriate opioid use and demonstrates the need for better application of guidance and standards around opioid prescribing practices.</p>
2019 Harbaugh & Suwanabol	Optimizing pain control during the opioid epidemic	Literature Review	<p>Outline the relevance of the US opioid crisis to surgical prescribing, describe strategies for opioid reduction using a stepwise therapy approach, and provide recommendations for improving the safety of opioid prescribing. Additional recommendations for risk assessment and naloxone co-prescribing for high-risk patients are addressed.</p>	<p>Excessive or unmonitored opioid prescribing may increase risk of opioid misuse, addiction, overdose, and diversion into the community.</p> <p>A stepwise approach to multimodal pain management should be used, beginning with nonopioid medications for opioid-naïve patients, and adjuvant therapies to address concomitant symptoms, such as anxiety.</p> <p>Patients with chronic opioid use likely require dose escalation for acute pain but should be followed closely for adequate pain management and dose de-escalation when feasible.</p>

Pub. Year Author's Last Name	Title of Publication	Type of Study	Main Outcomes or Findings	Support for and or link to project
				Patients receiving an opioid prescription should be assessed for risk of opioid misuse or overdose, and naloxone co-prescribing should be considered for high-risk patients.
2020 Khan et al.	Narcan encounters: overdose and naloxone rescue experiences among people who use opioids	Qualitative study using semi-structured interviews	Four broad thematic categories were identified: (1) Overdose experience and memory: Most participants remembered taking the drugs one minute and waking up the next—sometimes in different surroundings (2) Naloxone rescue—waking up: Participants described acute withdrawal symptoms, disorientation, and volatile emotions (3) Reasons for overdose: Polypharmacy; changes in opioid tolerance, or presence of fentanyl were the most common explanations. (4) Impacts of naloxone rescue: A variety of contextual factors influenced participants' responses to naloxone rescue, especially acute withdrawal symptoms.	Results suggest that a naloxone rescue may not be a wake-up call for many people who use opioids, but access to naloxone is an effective overdose harm reduction option, supporting its widespread implementation. The study findings underscore the importance of ongoing community overdose prevention and harm reduction initiatives, including take-home naloxone (THN) and medication assisted treatment in the Emergency Department.
2015 Khelemsky et al.	Incidence and demographics of post-operative naloxone administration: a 13-year experience at a major tertiary teaching institution	Retrospective cohort study	To characterize the demographics of patients receiving postoperative naloxone, as well as the incidence of administration in the first 72 post-operative hours at a large urban academic medical center in the United States This trial examined all operative cases requiring inpatient admission performed at	Naloxone is a competitive opioid antagonist typically administered to reverse opioid-induced respiratory depression. Postoperative administration of naloxone may be considered a proxy for significant postoperative opioid-induced respiratory depression and data regarding its use may be utilized as a quality measure. Few large studies have been done to characterize the population and define the

Pub. Year Author's Last Name	Title of Publication	Type of Study	Main Outcomes or Findings	Support for and or link to project
			<p>that institution in 2003. The incidence of naloxone administration was found to be 0.53%, however 25% were later found to have a new diagnosis that contributed to sedation</p> <p>Demographics of this group were older, ASA 3 women, qualifying as overweight, but not obese, undergoing elective surgery with a general anesthetic technique. Most cases of postoperative naloxone administration occurred within the first 24 hours.</p>	<p>incidence of naloxone administration in the postoperative inpatient setting.</p>
2019 Moride et al.	A systematic review of interventions and programs targeting appropriate prescribing of opioids	Systematic review	<ol style="list-style-type: none"> 1) Identify interventions that target opioid prescribing. 2) Assess and compare the effectiveness of interventions on opioid prescription and related harms. 3) Determine the methodological quality of evaluation studies. 	<p>Evidence of effectiveness of interventions targeting the prescription of opioids is scarce in the literature. Although PMPs have been associated with a reduction in the overall prescription rates of Schedule II opioids, their impact on the appropriateness of use taking into consideration benefits, misuse, legal and illegal use remains elusive. Our review suggests that existing interventions have not addressed all determinants of inappropriate opioid prescribing and usage. A well-described theoretical framework would be the backdrop against which targeted interventions or policies may be developed.</p>
2017 Meisenberg et al.	Implementation of solutions to reduce opioid-induced	Single-site retrospective review	A single-site retrospective review of eligible rescue naloxone cases was conducted to identify the causes of opioid-induced OSRD	Implementation of solution bundles that utilized an EMR to create meaningful clinical decision support and cultural changes related

Pub. Year Author's Last Name	Title of Publication	Type of Study	Main Outcomes or Findings	Support for and or link to project
	oversedation and respiratory depression		<p>in a hospital as well as to identify risk factors.</p> <p>A survey was used to assess potential opioid knowledge deficits among hospitalist prescribers.</p> <p>The primary endpoint of our analysis was naloxone use for documented cases of opioid-induced OSRD to determine the effectiveness of the interventions. A mean of 16 OSRD events occurred per quarter before intervention implementation.</p>	<p>to pain goals and communication about sedation level at an acute care hospital resulted in a fivefold reduction in OSRD events that has been sustained for two years.</p> <p>Deficiencies of clinical care were found in four inter-related domains: knowledge deficits, inadequate monitoring, failure to leverage the EMR, and cultural issues regarding pain assessments and sedation management- all highlighting the multifaceted nature of this problem.</p>
2019 Overcarsh et al.	Guidelines for monitoring patients using opioid therapy	Practice guidelines	<p>Practical recommendations are provided for clinicians caring for noncancerous patients on chronic opioid therapy. Recommendations are largely based on national consensus guidelines with a focus on frequency and content of follow-up, identification of high-risk behaviors, and reassessment of goals of treatment.</p>	<ul style="list-style-type: none"> - provides common components of controlled substance agreements - details risk of chronic opioid use
2018 Pozek et al.	Comprehensive acute pain management in the perioperative surgical home	Peer- reviewed journal article	<p>It was noted that regardless of whether the procedure was considered major or minor, 6% of patients filled opioid prescriptions between 90 and 180 days after surgery. The investigators propose that persistent opioid use may not simply be related to whether a procedure is considered major or minor, but is more likely due to addressable patient-level predictors, including preoperative</p>	<p>Establishing a perioperative surgical home (PSH) framework can lead to improved analgesic treatment of surgical patients through careful coordination of care.</p> <p>Perioperative administration of a multimodal analgesic plan, including nonopioid modalities and regional and neuraxial</p>

Pub. Year Author's Last Name	Title of Publication	Type of Study	Main Outcomes or Findings	Support for and or link to project
			<p>tobacco use, alcohol and substance abuse disorders, mood disorders, and preoperative pain disorders. ¹⁴ Many of these risk factors can be identified preoperatively by the physician anesthesiologist during the preoperative assessment visit. These can risk factors subsequently be addressed through either direct education interventions for tobacco cessation or partnership and consultation with psychological and psychiatric services to help reduce persistent postoperative opioid use.</p>	<p>anesthesia techniques, can minimize postsurgical pain.</p> <p>Severe postoperative pain along with other patient- and surgery-specific factors can lead to chronic postsurgical pain.</p> <p>A preoperative assessment by a physician anesthesiologist can identify patients with behavioral risk factors for persistent postoperative opioid usage and address concerns before surgery.</p>
2017 Rager & Schwartz	Defending opioid treatment agreements: Disclosure, not promises	Peer-reviewed journal article	<p>Most criticisms of opioid treatment agreements (OTAs) stem from a mistaken understanding of OTA's purpose and ethical basis.</p> <p>Informed consent is often conducted entirely verbally, such as when doctors prescribe medications or order lab tests. However, when the clinical situation is such that informing the patient of risks and benefits is particularly important, especially for interventions that pose serious risks, then written consent is required.</p>	<p>Consenting can inform the decision a patient makes about whether to accept the physician's offer to treat him or her with these medications. A patient who was considering such treatment might decide, after reading the OTA, to pursue other methods of treatment.</p> <p>This perspective highlights the role that OTAs play in supporting fully informed consent. A number of critics acknowledge that an OTA may appear to play a role in informed consent, since it discloses risks, benefits, and alternatives to controlled medications</p>
2015 Soto & Yaldou	The Michigan opioid safety score (MOSS): A patient safety and	Validation study	The recently developed Michigan Opioid Safety Score integrates health risks and objective measures of respiratory rate and	Outline ongoing problems with pain control including education, standardization, and safety. Highlights the issue regarding

Pub. Year Author's Last Name	Title of Publication	Type of Study	Main Outcomes or Findings	Support for and or link to project
	nurse empowerment tool		sedation, while encouraging the use of multimodal analgesia for all patients.	insufficient monitoring of patients at risk for opioid related complications.
2016 Tobin et al.	Breaking the pain contract: A better controlled substance agreement for patients on chronic opioid therapy	Peer reviewed Journal article	“Pain contracts” for patients receiving long-term opioid therapy, though well intentioned, often stigmatize the patient and erode trust between patient and physician. This article discusses how to improve these agreements to promote adherence, safety, trust, and shared decision making.	- summarizes the pros/cons of criticisms of contractual agreements regarding opioid use between patients and providers and provides considerations for the best outcome with supporting research study findings.

REFERENCES

- American Academy of Pain Medicine. (n.d.) *Sample informed consent: Opioid therapy for chronic pain*. <https://www.painmed.org/Workarea/DownloadAsset.aspx?id=3211>
- Arizona Department of Health Services (n.d.). *Arizona opioid action plan version 2.0*. <https://azdhs.gov/documents/prevention/health-systems-development/epidemic/opioid-action-plan-2019-2021.pdf>
- Arizona Department of Health Services. (2017). *Opioid enhanced surveillance*. AZDHS.gov. <https://azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid-prevention/talking-points-public-data.pdf>
- Arizona Department of Health Services. (2018). *2018 Opioid deaths and hospitalizations*. <https://www.azdhs.gov/documents/prevention/health-systems-development/epidemic/2018-opioid-death-hospitalizations.pdf>
- Arizona Department of Health Services. (2020). *Opioid epidemic*. <https://azdhs.gov/prevention/womens-childrens-health/injury-prevention/opioid-prevention/index.php>
- Arizona Office of Tourism. (2020). *American Indian tribal lands*. AZ.Gov. <https://www.visitarizona.com/places/american-indian/>
- Agency for Healthcare Research and Quality (AHRQ). (2018). *Opioids: AHRQ works. Building bridges from research to practice*. AHRQ Publication No. 19, 18(12). <https://www.ahrq.gov/opioids/about.html>
- Bartels, K., Mayes, L. M., Dingmann, C., Bullard, K. J., Hopfer, C. J., & Binswanger, I. A. (2016). Opioid use and storage patterns by patients after hospital discharge following surgery. *PloS One*, *11*(1), e0147972. <https://doi.org/10.1371/journal.pone.0147972>
- Batras, D., Duff, C., & Smith, B. J. (2016). Organizational change theory: Implications for health promotion practice. *Health Promotion International*, *31*(1), 231-241. <https://doi.org/10.1093/heapro/dau098>
- Brant, J. M., Stringer, L., Jurkovich, L. R., Coombs, N. C., Mullette, E. J., Buffington, C., ... & Karera, D. (2018). Predictors of oversedation in hospitalized patients. *American Journal of Health-System Pharmacy*, *75*(18), 1378-1385.
- Calcaterra, S. L., Drabkin, A. D., Leslies, S. E., Doyle, R., Koester, S., Frank, & ... Binswanger, I. A. (2017). The hospitalist perspective on opioid prescribing: A qualitative analysis. *Journal of Hospital Medicine*, *11*(8), 536-542. doi:10.1002/jhm.2602

- Calcaterra, S. L., Yamashita, T. E., Min, S. J., Keniston, A., Frank, J. W., & Binswanger, I. A. (2016). Opioid prescribing at hospital discharge contributes to chronic opioid use. *Journal of General Internal Medicine*, 31(5), 478-485. <https://doi.org/10.1007/s11606-015-3539-4>
- Carlson, R. G., Nahhas, R. W., Martins, S. S., & Daniulaityte, R. (2016). Predictors of transition to heroin use among initially non-opioid dependent illicit pharmaceutical opioid users: A natural history study. *Drug Alcohol Depend*, 160, 127-134. doi:10.1016/j.drugalcdep.2015.12.26
- Centers for Disease Control and Prevention. (n.d.) *Calculating total daily dose of opioids for safer dosage* [infographic]. https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf
- Centers for Disease Control and Prevention. (1999). Framework for program evaluation in public health. *Morbidity and Mortality Weekly Report*, 48(11), 1-42. <https://www.cdc.gov/eval>
- Centers for Medicare and Medicaid Services. (2017). *42 CFR Parts 414, 416, 419, 482, 486, 488, and 495*. U.S. Department of Health and Human Services. <https://federalregister.gov/d/2016-26515>
- Centers for Disease Control and Prevention. (2018). *Opioid overdoses treated in emergency departments: Identify opportunities for action*. <https://www.cdc.gov/vitalsigns/opioid-overdoses/index.html>
- Center for Disease Control and Prevention. (2020). *The drug overdose epidemic: Behind the numbers*. <https://www.cdc.gov/drugoverdose/data/index.html>
- Chakravarthy, B., Somasundaram, S., Mogi, J., Burns, R., Hoonpongsimanont, W., Wiechmann, W., & Lotfipour, S. (2018). Randomized pilot trial measuring knowledge acquisition of opioid education in emergency department patients using a novel media platform. *Substance Abuse*, 39(1), 27-31. <https://doi.org/10.1080/08897077.2017.1375061>
- Chapman, L., De la Cruz, A. M., & Hutto, J. (2017). Opioid treatment agreements: Helpful or hurtful? *American Journal of Psychiatry Residents' Journal*, 11(76), 14-16.
- Costello, M. (2015). Prescription opioid analgesics: Promoting patient safety with better patient education. *American Journal of Nursing*, 115(11), 50-56. doi:10.1097/01.NAJ.0000473315.02325.b4
- Cummings, S., Bridgman, T., & Brown, K. (2016). Unfreezing change as three steps: Rethinking Kurt Lewin's legacy for change management. *Human Relations*, 69(1), 33-60. doi:10.1177/0018726715577707

- Dignity Health. (n.d.) *About us*. <https://www.dignityhealth.org/arizona/locations/stjosephs/about-us>
- Drug Enforcement Agency. (2016). *DEA reduces amount of opioid controlled substances to be manufactured in 2017*. <https://www.dea.gov/sites/default/files/public-inspection.federalregister.gov/2016-23988.pdf>
- Florence, C. S., Zhou, C., Luo, F., & Xu, L. (2016). The economic burden of prescription opioid overdose, abuse, and dependence in the United States. *Medical Care*, *54*(10), 901-906. doi:10.1097/MLR.0000000000000625
- Glauser, J. & Money, S. (2018). Medical management of pain in the emergency setting without narcotics: Current status and future options. *Current Emergency and Hospital Medicine Reports*, *6*(4), 134-140.
- Glowacki, D. (2015). Effective pain management and improvements in patients' outcomes and satisfaction. *Critical Care Nurse*, *35*(3), 33-43.
- Green, C. A., Perrin, N. A., Hazelhurst, B., Janoff, S. L., DeVeaugh-Geiss, A., Carrell, D. S., ... & Coplan, P. M. (2018). Identifying and classifying opioid related overdoses: A validation study. *Pharmacoepidemiology and Drug Safety*, *28*(8), 1127-1137.
- Gupta, A., Lee, L. K., Mojica, J. J., Nairizi, A., & George, S. J. (2014). Patient perception of pain care in the United States: A 5-year comparative analysis of hospital consumer assessment of health care providers and systems. *Pain Physician*, *17*(5), 369-377.
- Guy, G. P., Zhang, K., Bohn, M. K., & Dowell, D. (2017). Vital signs: Changes in opioid prescribing in the United States, 2006-2015. *Morbidity and Mortality Weekly Report*, *66*(26), 697-704. doi:http://dx.doi.org/10.15585/mmwr.mm6626a4
- Harbaugh, C. M. & Suwanabol, P. A. (2019). Optimizing pain control during the opioid epidemic. *Surgical Clinics*, *99*(5), 867-883.
- Healthcare Cost and Utilization Project. (2020). *HCUP fast stats: Opioid hospital use map*. www.hcup-us.ahrq.gov/faststats/opioid/opioidusemap.jsp.
- Kahn, L. S., Wozniak, M., Vest, B. M., & Moore, C. (2020). "Narcan encounters:" Overdose and naloxone rescue experiences among people who use opioids. *Substance Abuse*, 1-14.
- Kelly, S., Johnson, G. T., & Harbison, R. D. (2016). Pressured to prescribe: The impact of economic and regulatory factors on South-Eastern ED physicians when managing the drug-seeking patient. *Journal of Emergencies, Trauma, & Shock*, *9*(2), 58-63.

- Khelemsky, Y., Kothari, R., Campbell, N., & Farnad, S. (2015). Incidence and demographics of post-operative naloxone administration: a 13-year experience at a major tertiary teaching institution. *Pain Physician*, 18(5), E827-E829.
- Leung, P. T., Macdonald, E. M., Stanbrook, M. B., Dhalla, I. A., & Juurlink, D. N. (2017). A 1980 letter on the risk of opioid addiction. *New England Journal of Medicine*, 376(22), 2194-2195.
- Lewin, K. (1958). *Group decision and social change*. Readings in Social Psychology, eds. E. E. Maccoby, T. M. Newcomb and E. L. Hartly, Holt, Rinehart and Winston, New York pp. 197-211.
- Lewin, K. (1947), Frontiers in-group dynamics: II. Channels of group life, social planning and action research. *Human Relations*, 1(2), 143-153.
http://lhc.ucsd.edu/MCA/Mail/xmcamail.2013_07.dir/pdfef83xvxgaM.pdf
- McCarthy, D. M., Courtney, D. M., Lank, P. M., Cameron, K. A., Russell, A. M., Curtis, L. M. ... & Wolf, M. S. (2017). Electronic medication complete communication strategy for opioid prescriptions in the emergency department: Rationale and design for a three-arm provider randomized trial. *Contemporary Clinical Trials*, 3(59), 22-29.
<https://doi.org/10.1016/j.cct.2017.05.003>
- Meisenberg, B., Ness, J., Rao, S., Rhule, J., & Ley, C. (2017). Implementation of solutions to reduce opioid-induced oversedation and respiratory depression. *American Journal of Health-System Pharmacy*, 74(3), 162-169.
- Moride, Y., Lemieux-Uresandi, D., Castillon, G., Soares de Moura, C., Pilote, L., Faure, M., & Bernartsky, S. (2019). A systematic review of interventions and programs targeting appropriate prescribing of opioids. *Pain Physician*, 22(1), 229-240.
- National Institute on Drug Abuse. (2015). *Research report series: Prescription opioids and heroin*. https://www.drugabuse.gov/sites/default/files/rx_and_heroin_rrs_layout_final.pdf
- National Institute on Drug Abuse. (2016). *Opioid overdose crisis*.
<https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis>
- Office of National Drug Control Policy. (2017). *The president's commission on combating drug addiction and the opioid crisis*.
<https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Meeting%20Draft%20of%20Final%20Report%20-%20November%201%2C%202017.pdf>
- Overcarsh, P., Harvey, L., & Yunker, A. (2019). Guidelines for monitoring patients using opioid therapy. *Clinical Obstetrics & Gynecology*, 62(1), 59-66.

- Pett, M. A. (2015). *Nonparametric statistics for health care research: Statistics for small samples and unusual distributions*. Sage Publications
- Porter, J. & Jick, H. (1980). Addiction rare in patients treated with narcotics. *The New England Journal of Medicine*, 302(2), 123. <https://doi.org/10.1056/nejm198001103020221>
- Portenoy, R. K. & Foley, K. M. (1986). Chronic use of opioid analgesics in non-malignant pain: report of 38 cases. *Pain*, 25(2), 171-86. <https://www.ncbi.nlm.nih.gov/pubmed/2873550>
- Pozek, J. P. J., De Ruyter, M., & Khan, T. W. (2018). Comprehensive acute pain management in the perioperative surgical home. *Anesthesiology Clinics*, 36(2), 295-307.
- Rager, J. B., & Schwartz, P. H. (2017). Defending opioid treatment agreements: Disclosure, not promises. *Hastings Center Report*, 47(3), 24-33.
- Rathlev, N., Almomen, R., Deutsch, A., Smithline, H., Li, H., & Visintainer, P. (2016). Randomized controlled trial of electronic care plan alerts and resource utilization by high frequency emergency department users with opioid use disorder. *The Western Journal of Emergency Medicine*, 17(1), 28-34. <https://doi.org/10.5811/westjem.2015.11.28319>
- Soto, R. & Yaldou, B. (2015). The Michigan opioid safety score (MOSS): A patient safety and nurse empowerment tool. *Journal of PeriAnesthesia Nursing*, 30(3), 196-200.
- Stepan, J. G., Lovecchio, F. C., Premkumar, A., Kahlenberg, C. A., Albert, T. J., Baurley, J. W., & Nwachukwu, B. U. (2019). Development of an institutional opioid prescriber education program and opioid-prescribing guidelines: Impact on prescribing practices. *The Journal of Bone & Joint Surgery*, 101(1), 5-13. <http://dx.doi.org/10.2106/JBJS.17.01645>
- Tobin, D. G., Keough Forte, K., & Johnson McGee, S. (2016). Breaking the pain contract: A better controlled-substance agreement for patients on chronic opioid therapy. *Cleveland Clinic Journal of Medicine*, 83(11), 827-835.
- U.S. Census Bureau. (2016). *The 15 most populous cities: 2016*. Census.gov. <https://www.census.gov/content/dam/Census/newsroom/releases/2017/cb17-81-table3-most-populous.pdf>
- U.S. Census Bureau. (2019). *Quick facts: Phoenix city, Arizona*. Census.gov. <https://www.census.gov/quickfacts/fact/table/phoenixcityarizona/PST045219#>
- U.S. Department of Health and Human Services. (2018). *Quality id #131: Pain assessment and follow-up*. https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2019_Measure_131_MIPSCQM.pdf

- Vivolo-Kantor, A. M., Seth, P., Gladden, R. M., Mattson, C. L., Baldwin, G. T., Kite-Powell, A., & Coletta, M. A. (2018). Vital signs: Trends in emergency department visits for suspected opioid overdoses - United States, July 2016-September 2017. *MMWR. Morbidity and Mortality Weekly Report*, *67*(9), 279-285. <https://doi.org/10.15585/mmwr.mm6709e1>
- Vowles, K. E., McEntee, M. L., Julnes, P. S., Frohe, T., Ney, J. P., & van der Goes, D. N. (2015). Rates of opioid misuse, abuse, and addiction in chronic pain: A systematic review and data synthesis. *Pain*, *156*(4), 569-576. doi:10.1097/01.j.pain.0000460357.01998.f1
- Wheeler, E., Jones, T. S., Gilbert, M. K., & Davidson, P. J. (2015). Opioid overdose prevention programs providing naloxone to laypersons? United States, 2014-2015. *Morbidity and Mortality Weekly Report*, *64*(23), 631-635.
- Wilson, N., Kariisa, M., Seth, P., Smith, H. & Davis, N. L. (2020). Drug and opioid-involved overdose deaths: United States, 2017-2018. *Morbidity and Mortality Weekly Report*, *69*(11), 290-297.