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Effects of Trained Providers and Naloxone Distribution on Prescription Opioid Use Disorder

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
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Walden University
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Abstract

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PharmD, Howard University, 2014

MS, Trident University, 2012

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Public Health

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Abstract

Opioid abuse and overdose are associated with substantial morbidity and mortality rates, as well as social and economic costs. The purpose of this study was to evaluate the independent and interactive effects of state-sponsored prescription drug monitoring program (PDMP) trained healthcare providers and community-based naloxone distribution program related factors in the states of Florida and Georgia for the prevention and reduction of prescription opioid use disorder, overdose, and deaths. The research theory adopted was the socio-ecological model with an emphasis on risk factors such as age. The study used secondary data from 2014 to 2018 from the Florida and Georgia Departments of Health. The statistical analysis results from one-way ANOVA and multiple linear regression revealed that there is a direct association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of reported opioid overdoses, the number of opioid addiction treatment admissions, and the number of deaths attributed to opioid overdose-related deaths per year among adults 25 to 64 years. The results also showed that there is an association between community-based naloxone distribution, the number of reported opioid overdoses, the number of opioid addiction treatment admissions, and the number of deaths attributed to opioid misuse/overdose per year among adults 25 to 64 years. The positive social impact of the study is that PDMPs, the education of healthcare providers, community use of naloxone, and practice guidelines will reduce misuse, abuse, addiction, diversion, and false acquisition of prescription opioids.

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Dedication

I dedicate this study to my family especially my kids, close friends and professors for their enormous support and prayers throughout this journey. I am very grateful and give Almighty God all the glory.

Acknowledgments

I want to acknowledge my children and friends who encouraged and supported me throughout this course, I wish them all God's blessings.

I would also like to thank Dr. Nancy Rea, Dr. Cornelia White, Dr. Heba M. Athar, and Dr. Amany Refaat, for all their tireless support and assistance through their motivation and expertise to bring this project to successful completion.

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Section 1: Foundation of the Study and Literature Review

Introduction

The purpose of this study was to assess how various state-sponsored prescription drugs monitoring programs (PDMPs) training of healthcare providers on prescribing and dispensing of opioid drugs and community-based naloxone distribution program (CBNDP) events have contributed to the reduction of prescription drug use disorder and overdose. Opiate overdose persists as a significant public health problem, contributing to substantial morbidity and mortality among opiate users. In 2016, about 2 million Americans aged 12 and older admitted having an opioid use disorder (Rando et al., 2015; Reinhart et al., 2018). Drug overdose is currently one of the leading causes of preventable mortality in the United States (Rando et al., 2015). Opioids are the most common substances found in the single or poly cause of death (Rando et al., 2015).

Opioid overdose is one of the leading causes of injury-related death among Americans (age 25 to 64 years). From 1999 to 2018, there were more than 450,000 opioid overdose deaths. In 2018 alone, there were 47,000 opioid-related deaths in the US (Wilson et al. 2020). Approximately 45 deaths per day in the United States have been attributed to prescription opioids (Rando et al., 2015). Most of the overdose deaths are due to prescription opioid analgesics such as oxycodone, methadone, and hydrocodone (Li et al., 2014).

Opioid overdose is a significant public health concern that affects a diverse group of individuals across all categories of race, class, and geography. Opioid-related overdoses are spreading demographically and geographically such as from urban areas to suburban and rural regions. Research has shown that overdose mortality is on the rise

among non-Hispanic Whites, women, adolescents, young adults, and those with a history of chronic pain and depression (Colucci et al., 2014). Moreover, misuse and abuse of opioid analgesics have adverse health implications, including psychiatric illness (Colucci et al., 2014).

According to Patrick et al. (2016), over 47,000 people died in the United States from drug abuse in 2014 alone, and 61% of those deaths were prescription opioid related. It is estimated that prescription overdose fatalities represent 63% of all overdose mortalities (Rudd, 2016). Naloxone has been frequently used to pharmacologically reverse overdoses by emergency service workers as well as peers or family members of overdose victims (Abraham et al., 2017). It is best to intervene within an hour of the onset of overdose symptoms (Abraham et al., 2017).

The introduction of different state PDMPs with federal government funding assistance established statewide electronic databases of dispensed controlled substances (Li et al., 2014). Most states currently have (a) PDMPs, (b) prescription drug take-back days, (c) safe opioid prescribing guidelines, (d) education programs that seek to reduce opioid misuse and monitor and limit physicians and other healthcare providers on the number of opioids that can be prescribed or dispensed by using checks such as drug utilization review and prior authorization in insurance reimbursements, (e) mandatory use of state recommended guidelines and PDMPs, and (f) the distribution and administration of naloxone to at-risk patients (Faul et al., 2017). In this study, I sought to bring a positive change or social impact by seeking to inform and educate lawmakers, local authorities, and community leaders on the need to reduce and prevent prescription opioid use disorder and overdose in Florida and Georgia. This section includes the problem

statement, research questions, purpose of the study, literature review, definitions, assumptions, and delimitations.

Problem Statement

In recent years there has been an increase in the use of prescription opioids in the treatment of chronic non-cancer pain such as back pain and osteoarthritis despite the lack of long-term effectiveness and the risk of abuse (Centers for Disease Control and Prevention [CDC], 2019). According to the CDC (2019), opioid prescription overdose causes more than 34,000 deaths and 1.2 million emergency department visits annually. Most of the overdose deaths are due to prescription opioid analgesics such as oxycodone, methadone, and hydrocodone (Li et al., 2014).

In 2015, more than 12 million Americans reported misusing opioid pain relievers (Abraham et al., 2017). According to the CDC (2018), between 1999 and 2016, there were more than 630,000 deaths due to drug overdose. In 2016, about 42,000 drug overdose deaths involved an opioid (CDC, 2018). Additionally, it is estimated that about 115 Americans die daily from an opiate overdose (CDC, 2019).

More than three out of five drug overdose deaths involve an opioid (CDC, 2019). Overdose deaths from opioids, including prescription opioids and heroin, have increased by five times since 1999 (CDC, 2019). Over 50% of those deaths were from prescription opioids (CDC, 2019). It is also alarming to know that the annual number of prescriptions for opioid analgesics has increased from approximately 75 million to almost 210 million in the past 20 years (CDC, 2019).

The per capita consumption of prescription opioids has increased from 74 milligrams (mg) to 369 mg in the last decade; hence, an increase in overdose mortality

(Li et al., 2014). Furthermore, research shows that about 25 million people are involved in the non-medical use of pain relievers in the past decade (Rutkow et al., 2015). Overdose related deaths are concentrated among the poor, racial and ethnic minorities, and individuals cycling in and out of the criminal justice system (Rutkow et al., 2015).

Gap in Research

Research on naloxone distribution and prescription overdose is limited. Some policymakers have argued that providing naloxone to opiate abusers may increase opioid use and delay admission to treatment centers (see Doe-Smith, 2014; Rowe et al., 2015). PDMPs are created to monitor controlled prescription usage and consequently reduce opioid abuse (Rutkow et al., 2015). There are currently limited studies that demonstrate a statistically significant association between the two variables (Rutkow et al., 2015).

More so, studies evaluating the effectiveness of PDMPs in reducing opioid-related mortality are limited. Research evaluating the effectiveness of specific characteristics of PDMPs is also limited. This could be due to their variability from state to state. For instance, some states have more controlled substance schedules than the five schedules from the Drug Enforcement Agency (Faul et al., 2017). Other states do not classify codeine cough syrups as controlled substances (Patrick et al., 2016).

State policies could also contribute to the lack of research on the effectiveness of PDMPs. Some states mandate the registration and use of the PDMPs, while others only require periodic queries and specific algorithms to trigger a comprehensive investigation. The CDC guidelines on opioid prescribing, however, recommend the regular use of PDMPs (Finley et al., 2017; Leichtling et al., 2017).

The opioid epidemic is driven by overprescribing (Faul et al., 2017). Efforts to prevent prescription opioid overdose include the legislation of different state laws that limit physicians and other healthcare providers on the number of opioids that can be prescribed or dispensed, the use of checks such as drug utilization review, and prior authorization in insurance reimbursements (Faul et al., 2017). The use of state prescribing guidelines and PDMPs is however mandatory (Faul et al., 2017). Finally, the distribution and administration of naloxone to at-risk patients is also highly recommended (Faul et al., 2017).

Purpose of the Study

The purpose of this study was to evaluate and analyze how the number of state-sponsored PDMPs trained healthcare providers and CBNDP could affect the misuse, abuse, addiction, diversion and falsely acquiring of prescription opioids. This quantitative study emphasized objective measurements, the statistical, mathematical, or numerical analysis of data collected through manipulating pre-existing statistical data using computational techniques (see Frost, 2019). Healthcare provider education can reduce opioid prescribing by at least 40%, and result in fewer ER visits, leading to further reduction in opioid misuse, abuse, and addiction (Osborn et al., 2017)

The independent variables include: (a) the number of state-sponsored PDMP trained healthcare providers, (b) the number of naloxone community-based distribution center opioid prescriptions written per year, (c) the number of naloxone community-based distribution center prescriptions dispensed per year, (d) the number of naloxone community-based distribution center opioid prescriptions with MME above 90 written or

dispensed per year, and (e) naloxone community-based distribution center opioid naïve patients per year.

The dependent variables include: (a) the number of reported opioid overdoses per year among adults 25 to 64 years, (b) the number of opioid addiction treatment admissions per year, and (c) the number of opioid-related deaths per year among adults 25 to 64 years. Controlling variables include the age group of patients and the gender of the patients.

Research Questions and Hypotheses

RQ1: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of reported opioid overdoses per year among adults 25 to 64 years?

$H_0$1: There is no association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of reported opioid overdoses per year among adults 25 to 64 years.

$H_1$1: There is an association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of reported opioid overdoses per year among adults 25 to 64 years.

RQ2: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of opioid addiction treatment admissions per year among adults 25 to 64 years?

$H_0$2: There is no association between the number of state-sponsored PDMPs and the number of opioid addiction treatment admissions per year among adults 25 to 64 years.

$H_1$2: There is an association between the number of state-sponsored PDMPs trained physicians and the number of opioid addiction treatment admissions per year among adults 25 to 64 years.

RQ3: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of deaths attributed to opioid overdose-related deaths per year among adults 25 to 64 years?

$H_0$3: There is no association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of opioid overdose-related deaths per year among adults 25 to 64 years.

$H_1$3: There is an association between the number of state-sponsored PDMPs trained healthcare providers and the number of deaths attributed to opioid overdose-related deaths per year among adults 25 to 64 years.

RQ4: Is there an association between community-based naloxone distribution and the number of reported opioid overdoses per year among adults 25 to 64 years?

$H_0$4: There no association between community-based naloxone distribution and the number of reported opioid overdoses per year among adults 25 to 64 years.

$H_1$4: There is an association between community-based naloxone distribution and the number of reported opioid overdose per year among adults 25 to 64 years.

RQ 5: Is there an association between community-based naloxone distribution and the number of opioid addiction treatment admissions per year among adults 25 to 64 years?

$H_0$5: There is no association between community-based naloxone distribution and the number of opioid addiction treatment admissions per year among adults 25 to 64 years.

$H_1$5: There is an association between community-based naloxone distribution and the number of opioid addiction treatment admissions per year among adults 25 to 64 years.

RQ6: Is there an association between community-based naloxone distribution and the number of deaths attributed to opioid misuse/overdose per year among adults 25 to 64 years?

$H_0$6: There is no association between community-based naloxone distribution and the number of deaths attributed to opioid misuse/overdose per year among adults 25 to 64 years.

$H_1$6: There is an association between community-based distribution and the number of deaths attributed to opioid misuse/overdose per year among adults 25 to 64 years.

Theoretical Foundation for the Study

The theoretical base for this study focuses on the social ecological model (SEM), initially developed by Bronfenbrenner (1992). The theory stipulates that children's development is not only affected by their genetic or biological and psychological makeup, but also by their immediate physical and social environment, as well as the political and economic conditions in which they live in (Bukatko & Daehler, 2012). SEM is a multilevel framework which considers the different context and settings with which an individual interacts. It is based on the premise that individuals are influenced by their

relationships with others, the institutions, and the communities in which they belong (CAPT-SAMHSA, 2016).

The SEM theory has been used as a health promotion tool in many public health interventions, such as obesity, smoke cessation, and diabetes management (CDC, 2019). SEM theorists emphasized the interactions between the different levels of factors which are interdependence and how that affects the individual's health behavior. There are four levels to the SEM:

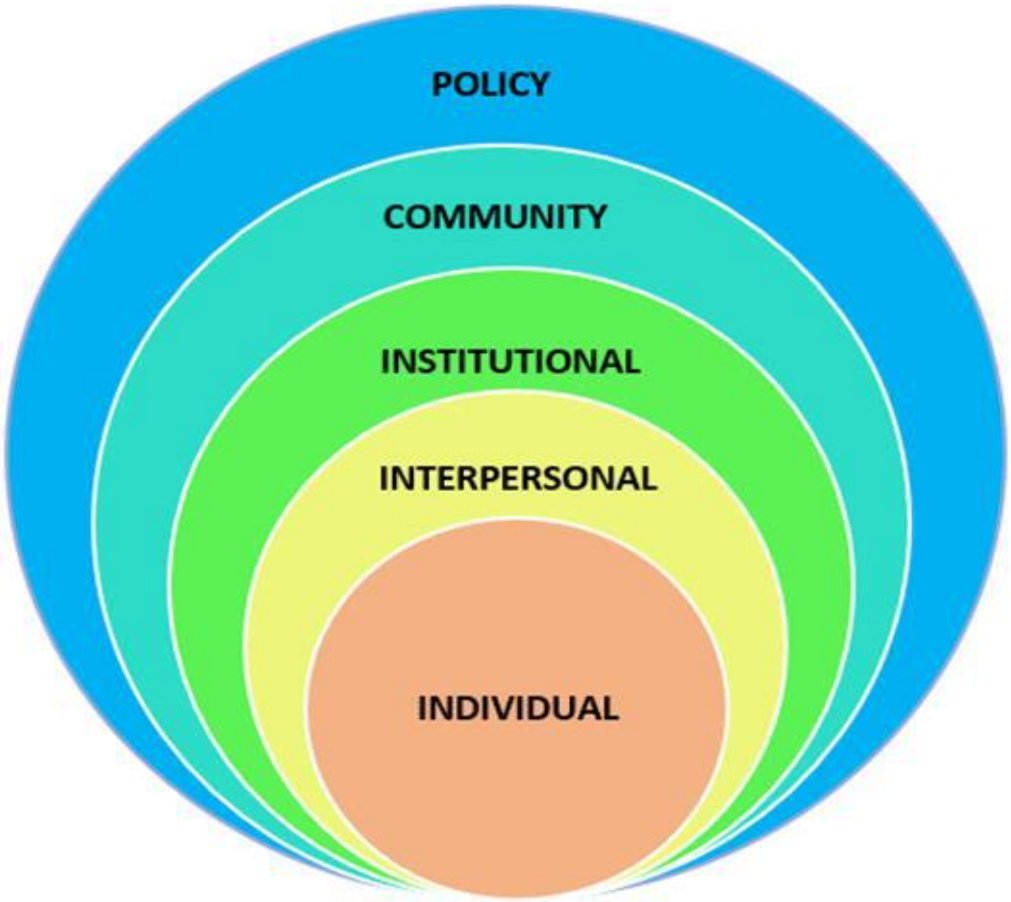
- Individual level: Includes factors specific to the individual, such as age, education, income, and psychosocial problems. The individuals would be educated by their healthcare providers when an opioid prescription is written or dispensed to their peculiar individual characteristics. They would also be educated on the need to keep a naloxone spray when opioids are prescribed since a few doses of opioid prescriptions could cause addiction or overdose.
- Relationship level: Includes an individual's closest circle (e.g. family members, peers, and teachers) who contribute to their range of experiences that may influence behavior. Young people's behavior is affected by the strong bond with their parents. This is because parents instill a sense of purpose in their children. These include the quest to aim high in life, finish school, get a degree, conform to school regulations, and be law-abiding citizens, among other values.
- Community level: Includes the settings in which social relationships occur, such as schools, workplaces, neighborhoods, and community norms. Other factors include residential mobility or instability, living in an urban

environment, and lack of social support or access to resources in dealing with prescription drug abuse/overdose.

- Societal level: Includes broader societal factors, such as social, religious, and cultural norms. Other social factors include health, economic, educational, social policies, law enforcement, public health education on drug abuse, availability of addiction treatment centers, state prescription opioid guidelines, prescription drug take-backs, state-sponsored PDMPs, CBNDPs, and health providers' continued education of effective pain management and drug abuse (CAPT-SAMHSA, 2016).

Figure 1

SEM Model. Adapted from Centers for Disease Control and Prevention; Division of Nutrition, Physical Activity, and Obesity (DNPAO)



(Available at https://www.cdc.gov/nccdphp/dnpao/state-local-programs/health-equity/framing-the-issue.html)

This study on state-sponsored PDMPs and CBNDPs considered all the socio-ecological factors that influence the individual's health behavior at all levels of the SEM to reduce the rate of prescription opioid overdose, decrease admissions to addiction treatment centers, and reduce overall overdose-related fatalities.

Nature of the Study

Study designs are essential for the quality, execution, and interpretation of public health research. The choice of study design however depends on funding, time constraints, availability of study participants, and prior research. I deemed the ecological

or correlation study design to be the appropriate observational study for this research. An ecological study design compares clusters of people based on their geographical location. Since this study purposed to use secondary data from the state-sponsored PDMPs's database, the ecological or correlation design was adopted. Ecological or correlation studies are also quick and inexpensive. Additionally, its analysis and presentation are simple and easy to understand. They are also noted to achieve a broader range of exposure levels than individual-level studies (Omair, 2015; Thiese, 2014).

This study's limitations include ecological fallacy or bias, that is, the lack of individual-level information and the inability to control confounders and possible inaccuracy of the data used. The unit of analysis is the population, not the individuals. This means any associations observed between the variables at the population level do not necessarily translate to the individual level (Aschengrau & Seage, 2014; Omair, 2015; Thiese, 2014).

The independent variables include the number of state-sponsored PDMPs trained healthcare providers, opioid prescriptions written and dispensed, the number of opioid prescriptions with morphine milligram equivalence (MME) above 90 milligrams, and the number of opioid naïve patients (patients who have never used prescription opioids or have not used prescription opioids in 6 months or more.)

The dependent variables include the number of reported opioid overdoses per year, the number of opioid addiction treatment admissions per year, and the number of opioid-related deaths per year among adults 25 to 64 years. The controlling variables include the age group and the gender of the patients.

Table 1

Research Questions, Dependent Variables, and Independent Variables

Research questions	Independent variables	Dependent variables
RQ 1: Is there an association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of reported opioid overdoses per year among adults 25 to 64 years?	The number of PDMP trained healthcare providers per year	The number of reported opioid overdoses per year
RQ 2: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of opioid addiction treatment admissions per year among adults 25 to 64 years?	The number of PDMP trained healthcare providers per year	The number of opioid addiction treatment admissions per year
RQ 3: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of deaths attributed to opioid overdose-related deaths per year among adults 25 to 64 years?	The number of state-sponsored PDMPs trained healthcare providers per year	The number of opioid-overdose-related deaths per year
RQ 4: Is there an association between community-based naloxone distribution and the number of reported opioid overdoses per year among adults 25 to 64 years?	Community-based naloxone distribution (the number of opioid prescriptions written and dispensed) per year	The number of reported opioid overdoses per year
RQ5: Is there an association between community-based naloxone distribution and the number of opioid addiction treatment admissions per year among adults 25 to 64 years?	Community-based naloxone distribution (the number of opioid prescriptions with MME higher than 90mg)	The number of opioid addiction treatment admissions per year
RQ 6: Is there an association between community-based naloxone distribution and the number of deaths attributed to opioid misuse/overdose per year among adults 25 to 64 years?	Community-based naloxone distribution (the number of opioid naïve patients)	The number of opioid-related deaths per year

Literature Search Strategy

I used a literature search strategy to identify search engines and databases related to the research problem. The general search produced existing peer-reviewed papers as well as government reports on the opioid epidemic. I further searched the SAMSHA and CDC websites for data and information related to the research problem. The literature review was also done using peer-reviewed published articles found PubMed, Library of Congress, ECHBOST, and Medline with full-text abstracts, Cochran Library, Google Scholar, Pro-Quest Nursing and Allied Health Services, and CINAHL. The search terms included *prescription opioids, abuse, misuse of opioid therapy, drugs, narcotics, substance abuse, pain management, controlled substances monitoring and diversion, healthcare, emergency departments, naloxone distribution, prescription drug monitoring programs, overdose*, and *drug fatalities*.

The scope of the literature search included only peer-reviewed literature published within the last 5 years. Literature including primary research articles, literature review articles, secondary research articles with contents relating to either the clinical or economic effects of prescription opioid abuse, treatment, and overdose, and standing orders for naloxone distribution in various states and communities, as well as opioid overdose fatalities were selected and reviewed. The search however excluded non-English articles, newspaper articles, and non-peer-reviewed journals.

Literature Review Related to Key Variables and/or Concepts

This study sought to evaluate and analyze how various state-sponsored PDMP's and community-based naloxone distribution programs have contributed to the prevention or reduction of prescription drug abuse and overdose. The study considered independent

variables such as age, gender, neighborhoods, and geographical location. The dependent variables considered included the volume of opioid prescriptions prescribed and dispensed, the number of healthcare providers trained to use PDMPs and counsel patients on naloxone use. More so, the number of opioid naïve patients, the number of days for the supply of prescription opioids, the morphine milligram equivalence of the opioids prescribed as well as the opioid overdose mortalities were all considered.

Prescription opioid abuse is a growing public health threat especially to the United States of America (USA). Millions of Americans are struggling with prescription opioid abuse, with thousands losing their lives due to its overdose. Medical professionals directly or indirectly influence the prescription opioid abuse epidemic through their prescribing habits (SAMSHA, 2018). Opioid abuse is also associated with downstream cases of infections related to intravenous injections such as HIV/AIDS, Hepatitis B, and C endocarditis, pyogenic spinal infections, osteomyelitis, septic arthritis, and epidural abscess (Ronan & Herzig, 2016). Hospital admissions concerning prescription opioid misuse and dependence have nearly doubled between 2000 and 2012. The rate of opioid-related inpatient stay has increased from 136.8 per 100,000 population in 2005 to 224.6 per 100,000 population in 2014. During this same period, the rate of opioid-related emergency department visits increased by 99.4 percent, from 89.1 per 100,000 population in 2005 to 177.7 per 100,000 population in 2014 (Weiss et al., 2017).

According to the CDC, the number of opioid prescriptions has more than quadrupled since the nineties. Research shows that at least one in every four patients given prescription opioids for the management of non-malignant chronic pain develop some form

of opioid use disorder, risky behaviors, compulsive use, and physiological dependence (CDC, 2019; SAMSHA, 2019).

The National Institute on Drug Abuse (NIDA), in partnership with the Appalachian Regional Commission (ARC), are working together to address the dramatic increase in prescription opioid drug use in Appalachia. Research has shown that rural communities along the Appalachian are more likely to have a high incidence of opioid abuse, misuse, and overdose (Singhal et al., 2016).

Individuals who misuse and abuse opioids tend to live in rural areas and are generally older than heroin users who tend to live in urban areas. Unintentional opioid overdose deaths are more common among adults between the ages of 45 to 64 and are even higher among adults between the ages of 25 and 34 (Pualozzi, 2014). Increases in opioid overdose fatalities among older individuals are a significant factor in the increases in opioid prescribing rates. Research shows that people over the age of 65 are prescribed an average of two opioids per prescription when visiting their doctors (Pualozzi, 2014).

Prevention Interventions

Effective opioid abuse interventions must be directed towards the highest risk groups. Any form of intervention should involve the individual, family, friends, healthcare providers, community leaders, and law enforcement agencies (Paulozzi, 2014). Easy access to state-sponsored Prescription Drug Monitoring Programs (PDMPs) and availability of naloxone are also key factors to consider. Training of healthcare providers to identify at-risk patients and preventing opioid prescription misuse and abuse is a key strategy to be adopted in this fight (Volkow & McLellan, 2016).

According to the CDC (2019), people who are more likely to abuse prescription opioids exhibit certain physical and psychological behaviors, such as irritability, urgency, or anxiety. They frequently attempt to obtain prescription opioids from multiple providers and pharmacies, try to fill opioid prescriptions earlier than time, and continuously change healthcare providers.

Abuse-deterrent formulations use opioid antagonist agents and chemicals that induce unpleasant symptoms when taken excessively. Manufacturers also incorporate physicochemical properties into the drug, making it difficult to extract the active ingredients from the tablet or capsule (Coplan et al., 2016).

In 2010, the manufacturer of Oxycontin (oxycodone extended release) reformulated the drug with a polyethylene oxide matrix. This matrix hardens the tablets which creates physicochemical barriers to deter breaking, crushing, and dissolving, making it harder to extract oxycodone and decrease the rate of abuse (Coplan et al., 2016). Kentucky's rate of OxyContin abuse has reduced from 85% to 30% after the introduction of the reformulated drug. Data from the National Survey of Drug Use and Health (NSDUH) published by SAMSHA shows that past year initiation of non-medical use of OxyContin decreased by 18%, 37%, 26%, and 49% over the years from 2011 to 2014 respectively, relative to the 695,000 users in 2009 (Coplan et al., 2016). Patients with prescription opioids with a morphine milligram equivalence (MME) of 100mg/day or more are nine times at a higher risk of overdose compared to patients with 20mg/day or less (Coe & Walsh, 2016).

Socio-Economical and Behavioral Impact

According to the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), a survey from 2014 to 2015 shows that young adults aged 18 to 24 are more likely to misuse or abuse opioid prescription and alcohol than adults aged 25 to 64 years (Coplan et al., 2016; Rudd et al., 2016). Research shows that opioid abuse and overdose are associated with mental health disorders. People with mental health and behavioral issues such as mood disorders, major depression, dysthymia, mania, and hypomania, anxiety disorders (e.g. panic disorders with and without agoraphobia), social phobia, and generalized anxiety disorder are more vulnerable to opioid misuse and abuse.

Patients with a past medical history of substance abuse or prescription opioid use, mental health issues (e.g., PTSD, depression, anxiety) mentally demanding occupations, older adults, dysfunctional social environment, and lower self-efficacy are highly vulnerable to prescription opioid abuse (Chou et al., 2016; Currow et al., 2016; Denenberg & Curtis, 2016).

The complexity of prescription opioid misuse and abuse is further confounded by an individual's demographics such as age, sex, race/ethnicity, educational background, marital status, and household income (Denenberg & Curtis, 2016). The rise in prescription opioid misuse and abuse is mostly due to increasing therapeutic use, and newer varying prescribing guidelines in different states (Brady et al., 2017). According to the Treatment Episode Data Set, the treatment admission rate for individuals abusing prescription opioids has increased from 7 to 36 per 100,000 population between 1997 and 2007. Opioid-related deaths have also increased by more than 124% over the same period (Meyer et al., 2014).

Research shows that opioid misusers or abusers between the ages of 25 and 64 years are more likely to utilize medical services, such as the emergency department, mental health outpatient clinics, and inpatient hospitals (Meyer et al., 2014). According to the Drug Abuse Warning Network (DAWN), emergency department visits involving prescription opioid abusers increased by more than 100% from 2004 to 2008. According to the White House Budget Office, it is estimated that prescription drug abuse, days of work loss, healthcare providers visits/services, and criminal justice cost the government nearly 300 billion dollars annually (Meyer et al., 2014).

A recent meta-analysis by Brady et al. (2017), indicated that a higher proportion of males suffer from prescription opioid misuse, abuse, and overdose. Also, individuals of either gender, aged 25 to 54 are at the highest risk of abuse prescription opioids. Individuals afflicted with psychotic disorders or had widespread substance abuse issues were more likely to abuse prescription opioids (Brady et al., 2017).

All patients, including opioid-naïve patients, should be screened for potential risk of abuse before starting opioid therapy. Patients on opioid therapy should receive education regarding the safe use, storage, and disposal of prescription opioids. Also, taking the medications as directed, acquiring them from only one provider, not sharing drugs with friends and family, and not taking medications with alcohol are important precautions to be adhered to (Brady et al., 2016).

Long-term use of prescription opioids could precipitate the risk of tolerance, physical dependence, and withdrawal symptoms when stopped abruptly. Tolerance effects of medications cause the need to increase the currently prescribed dosages to be effective. Opioid withdrawal symptoms include sympathetic stimulation, elevated heart rate, and

blood pressure, pupillary dilation, goosebumps, anxiety, jittery behavior, nausea, diarrhea, runny nose, yawning, myalgia, and insomnia. These withdrawal symptoms could sometimes be treated with alpha-blocking agents like clonidine or tapering of opioid prescriptions (Chou et al., 2016; Currow et al., 2016; Denenberg & Curtis, 2016).

Concurrent use of opioids with neuron-depressants or sedation medications increases the risk of sedation, hypoventilation, falls, accidents, and sudden unintentional death. Long-term opioid therapy also increases the risk of cardio-respiratory events or myocardial infarction in patients with sleep apnea and end-stage respiratory disease (Chou et al., 2016; Currow et al., 2016; Denenberg & Curtis, 2016).

Research shows that as the dose of the prescription opioid increases, so does the risk of abuse or dependence. Higher doses are also associated with increased cases of worker's disability compensation. Prescribing doses less than 120 MME/daily reduces the rate of mortality due to overdose. Ideally, the appropriate dosing of prescription opioids is between 40 and 90 MME per day (Manchikanti et al., 2012).

Prescribing opioids to the elderly must be done with caution doses equal to or higher than 50 MME daily doubles their risk of falls and fractures. Furthermore, prescribing opioids to pregnant women increases the risk of congenital disabilities, neural tube defects, congenital heart defects, gastroschisis, poor fetal growth, neonatal opioid withdrawal syndrome, and stillbirths (Chou et al., 2016; Yazdy et al., 2013).

However, non-pharmacological interventions include relaxation, guided imagery, acupuncture, massage, acupressure, aromatherapy, reflexology, yoga therapy, music therapy, spiritual therapy, heat and cold therapy, electrotherapy, cognitive behavioral

therapy, exercise, physical therapy, and epidural and steroid injections (Denenberg & Curtis, 2016; Gregory, 2014; Hooten et al., 2013; Rosenberg, 2013).

Naloxone use

Naloxone is an opioid receptor antagonist with no potential for abuse, which reverses the effects of opioids in cases of respiratory depression and decreased consciousness during an overdose. Naloxone produces little detectable pharmacological action without the presence of an opioid agonist (Coe & Walsh, 2016; Doe-Simkins et al., 2014). Access to and the use of naloxone is an essential tool in prescription opioid overdose prevention. Distribution of naloxone is a safe, feasible, and effective intervention in community settings. Also, laypersons can safely administer intranasal naloxone after brief training (Drainoni et al., 2016). Distribution of naloxone to individuals who may witness an overdose through community-based naloxone and overdose education programs have shown a reduction in overdose deaths in these communities (Jones et al., 2016).

Recent legislative changes in several states have however allowed naloxone to be administered by first responders, law enforcement officers, healthcare providers, family members, and friends, as well as bystanders to an opioid, overdosed individual (Abuse, 2018; Coe & Walsh, 2016). Naloxone could also be dispensed to patients with a history of overdose, substance abuse disorder, or those prescribed opioid medications (Abuse, 2016; Currow et al., 2016).

Community-based distribution of naloxone in combination with proper prescription opioid therapy decreases prescription overdose risk and mortality (Walley et al., 2013). Many states now have "Standing Orders" (agreements with pharmacies and hospitals to dispense naloxone to patients without a prescription) (Drainoni et al., 2016).

Project Lazarus, a community-based overdose prevention program in Wilkes County North Carolina, has recorded a 50% reduction in opioid-related deaths since its inception. The program engages local prescribers, pain patients, and various non-medical prescription opioid users to reduce opioid abuse and overdose. The program advocates and offers naloxone as part of routine medical care to suspected prescription opioid abusers and pain patients who are at high risk for overdose (Coe & Walsh, 2016; Doe-Simkins et al., 2014).

Naloxone dispensing is recommended for individuals such as patients who have been recently prescribed or treated with prescription opioids, suspected or confirmed history of non-medical opioid use, or patients with a high dose of opioid prescription (doses =100 MME) (Coe & Walsh., 2016). It is also recommended for opioid naïve patients who have prescribed methadone, patients just recently released from prison, or mandatory abstinence drug detox/program. Also, patients who have respiratory issues or disease (e.g. asthma, COPD, emphysema, sleep apnea, smoker) are prescribed opioids (Coe & Walsh, 2016; Doe-Simkins et al., 2014). Naloxone could also be dispensed to patients with a history of alcohol or harmful substance abuse, abuse of benzodiazepines, psychiatric disorders, or cognitive impairments who are prescribed opioids (Coe & Walsh, 2016).

From 2013 to 2015, naloxone prescriptions dispensed in the United States has increased more than ten (10) times. The same period notes a 187% increase in naloxone kit distributed by community-based organizations, which have resulted in a 160% increase in opioid overdose reversals (Jones et al., 2016).

Meanwhile, the significant adverse effect of naloxone in opioid-dependent patients is the occurrence of withdrawal symptoms after administration due to the rapid

displacement of opioid agonists from the opioid receptors. However, naloxone has no abuse potential or psychoactive properties when used for long-term (Mueller et al., 2015).

The potential issue of stigma and mistrust that may surround naloxone prescribing can be avoided by educating patients on the risk of respiratory depression from prescription opioid use. The notion that prescription opioid abusers see naloxone as a "safety net," and hence increase opioid abuse, risky behaviors, and delay entry into addiction treatment is false and has no scientific evidence (Coe & Walsh, 2016; Doe-Simkins et al., 2014).

Prescription Drug Monitoring Programs

Prescription Drug Monitoring Programs (PDMPs) are intended to detect and reduce abuse, misuse, and diversion of controlled substances to reduce associated harm as well as provide necessary information to enable healthcare providers offer appropriate medical care (Paulozzi et al., 2012; Islam & McRae 2014).

The PDMPs also collect information on the individual patient's such age, gender, payment method (e.g. insurance or cash), and the dispensing facility. They also give information on the rate of prescribing and dispensing by both prescribers and pharmacies, and on individuals receiving a combination of controlled substances such as opioids and benzodiazepines. Data from the PDMP can help identify patients at risk of addiction as well as those who might be diverting controlled substances. Such individuals tend to shop from multiple providers and obtain controlled substances from different pharmacies in a relatively short period. Research shows that effective PDMP increases clinicians' confidence in opioid prescribing, help identify and reduce doctor shopping, and monitor patients involved in opioid dependency treatment (Coplan et al., 2016).

The effectiveness of PDMP could be assessed by monitoring the system and its interoperability with other state programs such as addiction treatment centers (Coplan et al., 2016). In a survey conducted by Liebling et al. (2016), out of 200 participants, about 42% of people who misuse or abuse prescription opioids are classified as self-treaters whose main objective is to relieve pain. The survey also found that 24% of the participants use prescription opioids for recreational purposes, whiles 34% are mixed users (self-treaters and recreational users). Research shows that recreational and mixed users are more likely to be alcohol and illicit drug abusers (Coplan et al., 2016). Due to the interaction between opioids and certain psychiatric medications such as benzodiazepines, barbiturates, and other antidepressants, psychiatric patients are at increased risk of opioid overdose.

PDMPs ensure the appropriate use of controlled substances and detect diversion of controlled substances. The information on demographic and geographical locations of potential abusers enables public health providers to effectively implement intervention programs (Brady et al., 2016).

Studies show that Florida had more than 80% increases in prescription drug overdose deaths from 2003 to 2009 due to the abundance of pill mills. This was primarily caused by doctor offices, clinics, or pharmacies, which prescribe and dispense controlled medications to individuals with no legitimate medical purpose (Rutkow et al., 2015; Delcher et al., 2015).

In Florida, the acquisition and distribution of opioid prescriptions, regarding MME dropped by approximately 36% during the same period. It is also reported that the rate of oxycodone diversion in Florida declined by 29% in the quarter after PDMP implementation. From 2010 to 2012, oxycodone prescribing declined by 52.1%, and

oxycodone-caused mortality decreased by 25% within the same period (Delcher et al., 2015).

Definitions

Addiction

- It is a chronic disease of brain reward, motivation, and memory circuitry, which is characterized by a person's inability to abstain consistently, impaired behavior control, craving, and a dysfunctional emotional response (Lin, 2013).

Doctor shopper

- This is when a patient seeks prescriptions from multiple providers without revealing to each prescriber that other sources are involved. Individuals visiting more than one provider and pharmacy for opioids during a specified period provide the basis for this characterization. For example, an individual who uses more than five prescribers for the same schedule of opioids in one calendar year is referred to as a doctor shopper (Wilsey et al., 2013).

Drug misuse

- This is the use of a drug for purposes for which it was not intended or using a drug in excessive quantities. It is the use of controlled drugs with higher doses, or for a more extended period than prescribed or the use of a prescription for a reason other than the condition for which they were prescribed (Wise & Koob, 2014).

Opioid addiction

- It is the powerful, compulsive urge to use opioid drugs even when they are no longer required medically (Wise & Koob, 2014).

Opioid dependence

- This occurs when people consume opioids over a long period and develop physical and psychological withdrawal symptoms such as muscle cramping, diarrhoea, and anxiety (Wise & Koob, 2014).

Opioid overdose

- This happens when there are so many opioids or a combination of opioids and other drugs in the body that the victim is not responsive to stimulation, and breathing is inadequate (Harm Reduction Coalition, 2018).

Unintentional poisoning

- This involves the use of drugs or chemicals for recreational purposes in excessive amounts.

Standing Order

- This is a written document formulated collectively by the professional members of a department or healthcare facility that could contain rules, policies, procedure, regulations, or prescription orders for patient care (Lin, 2013).

Assumptions

The study assumes that strict and accurate application of the state-sponsored PDMP regulations, as well as the availability of affordable and easily accessible naloxone by patients at risk or their relatives, would result in a decrease in prescription opioid abuse and overdose. This assumption is because the state reports on prescription opioid addiction treatment and admissions decreased with the implementation of state-sponsored PDMPs and the availability of naloxone in many states.

Scope and Delimitations

Research shows that healthcare providers often lack the confidence to safely prescribe opioid prescriptions or the ability to detect potential prescription opioid misuse or abuse. They also lack the initiative or expertise to discuss the topic and consequences of prescription opioid misuse or abuse with patients. Even though healthcare providers acknowledge the use of prescription opioids to relieve moderate to severe pain, they have a more significant concern about opioid abuse or addiction (Hwang et al., 2015).

Some prescribers are reluctant to prescribe controlled substances due to fear of the legal repercussions. This results in the prescribing of alternative medications with less effectiveness or more significant side effects. There is however a lack of uniformity and knowledge in the use of opioid prescribing guidelines, as well as risk assessment tools to prevent prescription opioid abuse. More so, the requirements to register and access the PDMP information appears cumbersome to some healthcare providers, and interpretation of the information hinders progress in their work (Ringwalt et al., 2014; Rosenberg, 2013; Islam & McRae, 2014). In general, healthcare providers also lack experience and exposure to opioid-related events and thus fear regulators and law enforcement breathing down their necks (Abuse, 2018). There is the need to update guidelines across the state regularly and nationwide, and to further compare guidelines across neighboring states for uniformity (Abuse, 2018).

Patients fear the scrutiny from law enforcement if they use medications monitored by the PDMP. They might also worry about the additional cost of required monthly visits to the physician's office since such controlled drugs cannot be refilled without office visits. The monitoring system of PDMPs is seen as a breach of patient-physician confidentiality

or privacy. The public also views PDMP as a law enforcement tool rather than assisting in safe therapy management. It therefore involves additional time and puts pressure on the prescribers (Islam & McRae, 2014).

Research shows that young adults aged 18 to 25 use prescription opioids non-medically and are unwilling to seek treatment due to lack of trust and stigmatization. Additionally, healthcare professionals who happen to use prescription opioids non-medically refuse to seek treatment due to perceived discrimination and stigmatization. Other barriers include those inherent in the healthcare system such as treatment structure, waiting times, payment methods, and confidentiality (Liebling et al., 2016).

Significance, Summary, and Conclusions

Life expectancy in the U.S.A is affected by the high rates of mortality in people under 50 years of age who are dying due to unintentional drug overdose (Green et al., 2015). PDMPs help healthcare providers to identify potential abusers, doctor shoppers in different states and help to educate people on the need to use opioid prescribing guidelines to reduce opioid misuse (Reisman et al., 2009; Li et al., 2014). Currently, there have been about 644 community-based naloxone distribution programs in the U.S.A, with an estimate of over 27,000 overdose reversals annually (Green et al., 2015).

Research shows that emergency department visits involving misuse or abuse of prescription opioids have increased by 153% between 2004 and 2011 (Compton et al., 2016). Community-based programs in States such as New Mexico, Massachusetts, and New York have implemented successful naloxone distribution and overdose prevention programs for at-risk patients, family members, and bystanders (Green et al., 2015).

Research shows that community-based programs could result in about 74 % confirmed opioid overdose reversals (Rutkow et al., 2015).

Furthermore, there are currently many legislative changes in different states to increase naloxone access to those at risk of opioid overdose. Many states have also passed laws and issued standing orders that allow prescribers and pharmacists to prescribe and dispense naloxone to people other than the person at risk of overdose such as friends and family members of those at high overdose risk (Green et al., 2015).

Section 2: Research Design and Data Collection

Introduction

Opioid drug misuse and dependence is a major social and public health problem in the United States that has reached epidemic levels in the past few decades (Rudd et al., 2016). Indeed, about 2 million U.S. adults abused or were addicted to prescription opioids in 2014 (Hedden, 2015). Researchers have found that at least one in every four people who have received prescription opioids for pain not related to cancer become addicted at some point (Boscarino et al., 2015). Almost 50% of all deaths related to opioid misuse involve a prescription opioid (Kolodny et al., 2015).

It is clear that dependence on opioids inflicts enormous social and economic costs as a result of lost productivity, breakdown in relationships, healthcare costs, and expenses related to law enforcement. Prescription opioid misuse and dependence cost the U.S. economy a projected $78.5 billion (Florence et al., 2016).

In this study, data from 2014 to 2018 in Florida and in Georgia were compared and analyzed separately to assess the effect of state-sponsored PDMPs as well as the impact of naloxone standing orders and the availability of naloxone to at-risk patients or their relatives without prescription.

Research Design and Rationale

The study relied on using secondary data to determine the association between the implementation of state-sponsored PDMPs and prescription opioid abuse/overdose as well as the effect of state-issued standing orders to make naloxone readily available to people at risk.

An observational study was however the appropriate study design for this study. Observational studies can be used to study the effects of a broader range of exposures and diseases in the population to draw inferences on the prevention, treatment, and possible causes of the disease. This type of study also helps to provide information to explain the causes of disease incidence and the determinants of disease progression to predict the future healthcare needs of the population and to control diseases by studying ways to prevent them as well as prolong the lives of those who have the disease. The two main subtypes of observational study are descriptive and analytic studies (Aschengrau & Seage, 2014; Omair, 2015; Thiese, 2014).

The study also adopted the ecologic research design approach, which is an observational analytic study. In an ecological study, the unit of analysis is the group. The rate of exposure or exposed person and the rate of disease or the number of cases is known. However, the number of exposed cases is unknown. This study involves an assessment of the association between exposure rate (which is the availability of prescription opioids through written or dispensed prescriptions) and disease rate (which is the use/abuse and overdose) among different age groups and gender. This also includes finding out the incidence rates, prevalence rates, and mortality rates of the disease (Aschengrau & Seage, 2014; Omair, 2015; Thiese, 2014).

Ecologic studies are quick, simple to conduct, and inexpensive. However, the level of exposure of each individual in the unit being studied is not known. Besides, the overall ecologic trend or the correlational changes in the exposure and disease are reviewed.

The use of a quasi-experimental design was inappropriate for this study since it only gives information on whether the implementation or introduction of a public health program or policy was successful or failed. It also involves the manipulation of the study factors but not the randomization of the study subjects. Thus, it only evaluates the extent to which a program meets their public health goals (Aschengrau & Seage, 2014; Omair, 2015; Thiese, 2014).

The establishment of PDMPs through various state legislations and the granting of standing orders to dispense naloxone to at-risk patients have tremendously affected the abuse/overdose of prescription opioids. PDMPs and naloxone distribution have contributed to the slow down or curtailing of the opioid epidemic in the U.S. Many states now have laws that require providers and pharmacists to record any controlled substance prescription written or dispense within 24 hours of issuance. This allows current data to be accessed in the shortest possible time to determine the current trend of prescription opioid abuse/overdose. The data would also include the number of trained personnel who may use the PDMP program, such as licensed prescribers (which include optometrists, physicians, nurse practitioners, physician assistants, dentists, pharmacists, and law enforcement officers).

Methodology

This study adopted a quantitative research approach where existing data from various state health departments were collated and analyzed. The data included the annual reports for the last 5 years from the states PDMPs and drug overdose mortalities. Emails were sent to the various state's public health departments for quarterly and annual data on prescription opioid use and overdose, particularly from Florida and Georgia.

The Target Population

The population target is all patients in the states of Florida and Georgia who have prescribed opioid prescriptions in the past 5 years. The data includes personal data (i.e., age and gender) but not the patients' names, addresses, or any identifiable data to link a person's identity to this study.

The Sample Frame

The sample frame is all controlled substance prescriptions recorded in the states' PDMP data between the years 2014 and 2018 in Florida and Georgia. The PDMP collates all the controlled substance prescription data from both healthcare providers and pharmacies.

Sampling and Sampling Procedures

The sampling process for this study was done by using convenient sampling. Convenience sampling is a non-probability sampling technique where subjects are selected because of their convenient accessibility and proximity to the researcher. Data was therefore obtained from the PDMP annual reports from the department of health websites for the states of Florida and Georgia because that was the most convenient source of the data needed.

Data from the National Survey on Drug Use and Health (NSDUH) from the SAMSHA website with regard to Florida and Georgia were also collected. The NSDUH is a nationwide survey of civilian non-institutionalized population aged 12 years and older in the United States of America. The survey excludes individuals with no fixed household address, active-duty military personnel, and residents of institutional groups. The data collection method used by NSDUH included in-person interviews. Sampled

individuals were asked their willingness to report honestly about sensitive topics such as illicit drug use behavior and mental health issues. Confidentiality was emphasized in all written and oral communications with each respondent and their identities were protected. This was also ensured in cases where private interviews were performed using computer-assisted interviewing methods where researchers read questions from a computer or laptop and entered the responses.

Sample Size

The number of people interviewed in Florida in 2013 was 3,600 and in Georgia was 900. The number of people interviewed between 2014 and 2018 was 3,300 in Florida and 1,500 in Georgia. The selected age groups were 18-25, 26-34, 35-49, 50-64, and 65 or older, respectively. The sample was also made up of Hispanic, White, and Black respondents. The gender was male or female. Even though the NSDUH survey involved multiple questions on drug use and mental health, this study focused only on the opioid prescription data, which included hydrocodone, oxycodone, tramadol, codeine, morphine, fentanyl, hydromorphine, oxymorphine products, and methadone.

Instrumentation and Operationalization

Data from 2014 to 2018 provided by the PDMP program in Florida and Georgia were gathered. This was done by contacting the Electronic-Florida Online Reporting of Controlled Substance Evaluation (E-FORCSE) agency responsible for the state PDMP program in Florida and Georgia, the Epidemiology Section of the Department of Public Health accountable for the state PDMP program. The PDMPs collect prescription information on all controlled substances in the state. The DEA has five schedules for

controlled substances. The classification is based on the medication's potential for abuse, if it is accepted as a medical treatment, and the safety of its use, as follows:

- Schedule 1 drugs have the highest potential for abuse, but currently have no medical use and no safety use. Examples include heroin and cocaine.
- Schedule II drugs have a high potential for abuse and have current medical use but may lead to severe physical and psychological dependence. Examples include Oxycodone, Hydrocodone, and Ritalin.
- Schedule III drugs have the potential for abuse; they have medical use but may lead to moderate physical and psychological dependence. Examples include steroids and some codeine products.
- Schedule IV drugs have a low potential for abuse; they have medical use but may lead to limited physical and psychological dependence. Examples are Xanax, Ambien, and Tramadol.
- Schedule V drugs have a low potential for abuse; they have medical use but may lead to limited physical and psychological dependence. Examples are Lyrica and Lomotil.

In this study, I gathered data mainly on schedule II prescription opioids. The data contained the gender and age of the patients. However, all the personal identities of the patients were excluded. The age groups considered were adults 25 to 64 years. The data was coded and entered using the IBM SPSS version 25.0 (IBM, 2017). I conducted descriptive, inferential analysis of variance and multiple linear regressions of the variables in the research questions using the SPSS software.

Research Questions and Hypotheses

RQ1: Is there an association between the number of state-sponsored PDMPs trained health care providers per year and the number of reported opioid overdoses per year among adults 25 to 64 years?

$H_0$1: There is no association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of reported opioid overdoses per year among adults 25 to 64 years.

$H_1$1: There is an association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of reported opioid overdoses per year among adults 25 to 64 years.

RQ2: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of opioid addiction treatment admissions per year among adults 25 to 64 years?

$H_0$2: There is no association between the number of state-sponsored PDMPs and the number of opioid addiction treatment admissions per year among adults 25 to 64 years.

$H_1$2: There is an association between the number of state-sponsored PDMPs trained physicians and the number of opioid addiction treatment admissions per year among adults 25 to 64 years.

RQ3: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of deaths attributed to opioid overdose-related deaths per year among adults 25 to 64 years?

$H_0$3: There is no association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of opioid over dose-related deaths per year among adults 25 to 64 years.

$H_1$3: There is an association between the number of state-sponsored PDMPs trained healthcare providers and the number of deaths attributed to opioid overdose-related deaths per year among adults 25 to 64 years.

RQ4: Is there an association between community-based naloxone distribution and the number of reported opioid overdoses per year among adults 25 to 64 years?

$H_0$4: There no association between community-based naloxone distribution and the number of reported opioid overdoses per year among adults 25 to 64 years.

$H_1$4: There is an association between community-based naloxone distribution and the number of reported opioid overdose per year among adults 25 to 64 years.

RQ 5: Is there an association between community-based naloxone distribution and the number of opioid addiction treatment admissions per year among adults 25 to 64 years?

$H_0$5: There is no association between community-based naloxone distribution and the number of opioid addiction treatment admissions per year among adults 25 to 64 years.

$H_1$5: There is an association between community-based naloxone distribution and the number of opioid addiction treatment admissions per year among adults 25 to 64 years.

RQ6: Is there an association between community-based naloxone distribution and the number of deaths attributed to opioid misuse/overdose per year among adults 25 to 64 years?

$H_0$6: There is no association between community-based naloxone distribution and the number of deaths attributed to opioid misuse/overdose per year among adults 25 to 64 years.

$H_1$6: There is an association between community-based naloxone distribution and the number of deaths attributed to opioid misuse/overdose per year among adults 25 to 64 years.

Data Analysis Plan

Independent Variables

The independent variables include the number of state-sponsored PDMP trained healthcare providers, the number of naloxone community-based distribution center opioid prescriptions written and dispensed, the number of naloxone community-based distribution center opioid prescriptions with MME above 90, and the number of naloxone community-based distribution center opioid naïve patients (patients who have never used prescription opioids or have not used prescription opioids in 6 months or more).

Dependent Variables

The dependent variables include the number of reported opioid overdoses per year among adults 25 to 64 years, the number of opioid addiction treatment admissions per year, and the number of opioid-related deaths per year among adults 25 to 64 years.

Controlling variables include the age group and gender of the patients.

Table 2

Research Questions, Dependent Variables, and Independent Variables and Level of Measurement

Research questions	Independent variables	Dependent variables
RQ 1: Is there an association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of reported opioid overdoses per year among adults 25 to 64 years?	The number of PDMP trained healthcare providers per year/ Continuous	The number of reported opioid overdoses per year/ Continuous
RQ 2: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of opioid addiction treatment admissions per year among adults 25 to 64 years?	The number of PDMP trained healthcare providers per year/ Continuous	Number of opioid addiction treatment admissions per year/ Continuous
RQ 3: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of deaths attributed to opioid overdose-related deaths per year among adults 25 to 64 years?	The number of state-sponsored PDMPs trained healthcare providers per year/ Continuous	The number of opioid-overdose-related deaths per year/ Continuous
RQ 4: Is there an association between community-based naloxone distribution and the number of reported opioid overdoses per year among adults 25 to 64 years?	Community-based naloxone distribution (the number of opioid prescriptions written and dispensed) per year/ Continuous	The number of reported opioid overdoses per year/ Continuous
RQ5: Is there an association between community-based naloxone distribution and the number of opioid addiction treatment admissions per year among adults 25 to 64years?	Community-based naloxone distribution (the number of opioid prescriptions with MME higher than 90mg)/ Continuous	The number of opioid addiction treatment admissions per year/ Continuous
RQ 6: Is there an association between community-based naloxone distribution and the number of deaths attributed to	Community-based naloxone distribution (The number of opioid naïve patients)/ Continuous	The number of opioid-related deaths per

opioid misuse/overdose per year among adults 25 to 64 years?	year/ Continuous

The manipulation of the data was done using IBM's Statistical Package for Social Sciences. The research adopted descriptive statistics as one of its tools of analysis. Descriptive statistics describe the relationship between variables in a sample or population. Inferential statistics was also adopted to make inferences about the whole population as well as to measure the central tendencies to describe the rate of prevalence. The study also used the Analysis of Variance to assess if there is a significant difference between the variables. This was to help evaluate whether or not there is a between-group variability or within-group variability (error variance). The within-group variability is based on the random differences within the population.

Multiple regressions were also run with SPSS to find out whether or not there is a linear relationship between the dependent and independent variables, the presence of homogeneity, absence of outliers, standard distribution errors, as well as single variant and multivariate normality.

Non-parametric test is used when the assumption of normality is not met, and the sample means are not normally distributed. It is sometimes referred to as distribution-free tests.

Parametric test involves specific probability distributions (e.g., the normal distribution) and the tests involve estimation of the key parameters of that distribution (e.g., the mean or difference in means) from the sample data.

However, non-parametric tests may fail to detect a significant difference when compared to parametric analysis. The non-parametric test used in this study was the Mann-Whitney test. It is used to test the null hypothesis when two samples have the same median

or whether observations in one sample tend to be larger than observations in the other. The study also used the Kruskal-Wallis test to analyze the variance between the research variables. It analyses if there is any difference in the median values of three or more independent samples. The data values were ranked in increasing order, and the rank sums were calculated.

Threats to Validity and Reliability

Validity is the extent to which a concept is accurately measured in a quantitative study. There are three major types of validity: Content validity, Construct validity and Criterion Validity. Content validity is the extent to which a research instrument accurately measures all aspects of a construct. Construct validity is the extent to which a research instrument measures the intended construct. Criterion validity is the extent to which a research instrument is related to other instruments that measure the same variables (Heale & Twyross, 2015).

Internal validity relates to participants selection, data recording and data analysis of the data, while external validity refers to the generalizability of the study and whether it can be transferred to other populations (Lakshimi & Mohideen, 2013).

According to Drost (2011), internal validity refers to the validity of the study, as to whether there is a strong or causal relationship between the variables and the effects of any confounding factors. There are at least 12 threats to the internal validity of a study. These include history, maturation, testing, instrumentation, statistical regression, differential selection, experimental mortality, selection-maturation interaction, experimental treatment diffusion, compensatory equalization, rivalry, and demoralization.

On the other hand, external validity refers to the generalizability of the research findings. Some of the threats of external validity include:

- The extent to which one can generalize from the experimental sample to a defined population.
- The extent to which phonological variables interact with treatment variables.
- Explicit description of the experimental treatment and the Hawthorne effect
- Multiple-treatment interference
- Interaction of history and treatment effects.
- Measurement of the dependent variables and
- Interaction of time measurement and treatment effects.

According to Koziol and Arthur (2011), studies sponsored by the government generally involve larger samples that are more representative of the target population due to the availability of adequate funds, material, and human resources. State-sponsored agencies compiled the PDMP data with all the necessary elements. Due to this, the dataset had numerous variables; therefore, there was increased and strong statistical precision.

Reliability

The reliability and validity of research depend on the instruments used by the researchers to gather data. According to Drost (2011), reliability is the extent to which measurements are repeatable when different persons perform the analyses on various occasions under different conditions with alternative instruments that measure the same thing.

There are three types of reliability: test-retest reliability, inter-rater reliability and internal consistency reliability. Test-retest reliability evaluates the stability of measures administered at different times using the same individuals or the same standards. Inter-rater reliability establishes the equivalence of ratings obtained with an instrument when used by different observers. Reliable measurement will require consistency between different raters, and there should be no collaboration between raters. Inter-rater Reliability is determined by the coefficient of agreement of the judgment of the raters or Cohen's kappa. Internal consistency reliability gives an estimate of the equivalence of sets of items from the same test. The Coefficient of internal consistency or Cronbach's alpha is a function of the average inters correlations of items and the number of items in the scale. Its value is expressed from 0 to 1 (Drost, 2011; Lakshmi & Mohideen, 2013).

Most government and state-sponsored research have a Cronbach's alpha of at least 0.9. This study's data is extracted from reliable state data which is used in government policymaking. The validity and reliability of the data can be guaranteed since the population size is vast, and the data is also used for budgeting purposes. Thus, its accuracy can be assured.

Ethical Procedures

All the data collected are readily available to the public on the state's health department websites. The IRB requirement was to take the CITI program course for student researchers which was completed on Jan 9, 2019, and the NIH web-based training course for Protecting Human Research Participants, which was also completed on July 3, 2016.

Summary

In this section, the study sought to compare the retrospective secondary data using observational ecologic study. The ecologic research design considers the rate of exposure or exposed person and the rate of disease or the number of cases known. This study involves an assessment of the correlation between exposure rate (the availability of prescription opioids through written or dispensed prescriptions) and disease rate (the number of cases that use/abuse and/or overdose) by age group and gender. The data was taken from both national surveys by the NSDUH from SAMSHA and the websites of the state Department of Health in Florida and Georgia.

Section 3: Presentation of the Results and Findings

Introduction

The purpose of this chapter is to present the findings and analyses of the effects of state-sponsored PDMPs, trained healthcare providers, and community-based naloxone distribution in Florida and Georgia on the prevention and reduction of prescription opioid abuse and overdose. Prescription drug abuse and overdose are associated with substantial morbidity and mortality rates, as well as social and economic costs.

In this chapter, the variables explored were: the number of opioid prescriptions written in each year, the number of opioid prescriptions with MME above 90 per year, the number of opioid-naive patients (i.e. patients who have never used opioid prescriptions or have not used in the last 6 calendar months), the number of healthcare providers trained to use the PDMP in each year, the number of opioid-related emergency room visits and admissions each year, the number of opioid-related admissions into treatment centers each year, the number of opioid-related deaths each year, and the age and gender of the patients.

Data Collection and Analyses

The data for this study were collected from the Department of Public Health websites for both the State of Florida and Georgia from the years 2014 to 2018.

The research questions and hypotheses for the study are as follows:

RQ1: Is there an association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of reported opioid overdoses per year among adults 25 to 64 years?

$H_0$1: There is no association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of reported opioid overdoses per year among adults 25 to 64 years.

$H_1$1: There is an association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of reported opioid overdoses per year among adults 25 to 64 years.

RQ2: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of opioid addiction treatment admissions per year among adults 25 to 64 years?

$H_0$2: There is no association between the number of state-sponsored PDMPs and the number of opioid addiction treatment admissions per year among adults 25 to 64 years.

$H_1$2: There is an association between the number of state-sponsored PDMPs trained physicians and the number of opioid addiction treatment admissions per year among adults 25 to 64 years.

RQ3: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of deaths attributed to opioid overdose-related deaths per year among adults 25 to 64 years?

$H_0$3: There is no association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of opioid overdose-related deaths per year among adults 25 to 64 years.

$H_1$3: There is an association between the number of state-sponsored PDMPs trained healthcare providers and the number of deaths attributed to opioid overdose-related deaths per year among adults 25 to 64 years.

RQ4: Is there an association between community-based naloxone distribution and the number of reported opioid overdoses per year among adults 25 to 64 years?

$H_0$4: There no association between community-based naloxone distribution and the number of reported opioid overdoses per year among adults 25 to 64 years.

$H_1$4: There is an association between community-based naloxone distribution and the number of reported opioid overdose per year among adults 25 to 64 years.

RQ 5: Is there an association between community-based naloxone distribution and the number of opioid addiction treatment admissions per year among adults 25 to 64 years?

$H_0$5: There is no association between community-based naloxone distribution and the number of opioid addiction treatment admissions per year among adults 25 to 64 years.

$H_1$5: There is an association between community-based naloxone distribution and the number of opioid addiction treatment admissions per year among adults 25 to 64 years.

RQ6: Is there an association between community-based naloxone distribution and the number of deaths attributed to opioid misuse/overdose per year among adults 25 to 64 years?

$H_0$6: There is no association between community-based naloxone distribution and the number of deaths attributed to opioid misuse/overdose per year among adults 25 to 64 years.

$H_1$6: There is an association between community-based naloxone distribution and the number of deaths attributed to opioid misuse/overdose per year among adults 25 to 64 years.

Descriptive Demographics and Univariate Analysis of the Florida Sample

Data were collected from the Florida State Health Department's PDMP (Electronic-Florida Online Reporting of Controlled Substances Evaluation- E-FORSCE) website from the years 2014 to 2018. The variables were the total number of prescription opioid written per year from 2014 to 2018, the total number of yearly prescriptions with MME greater than 90mg (MME>90), the total number of yearly emergency room admissions and visits, the total number of healthcare providers trained per year, the total number of opioid naïve patients, and the number of prescription opioid written with daily MME > 90mg. The results are shown in Table 3.

Table 3

Florida PDMP Data

Year	2014	2015	2016	2017	2018
Number of opioid RXs	15,588,677	16,789,300	16,809,626	16,221,421	15,402,141
Total MME per opioid RXs	661	657	609.6	624.6	643.4
Number of ER visits & admissions	12,787	11,263	13,285	16,138	11,820
Number of providers trained in PDMP	14,029	46,992	34,290	27,621	41,217
Number of opioid naïve patients	7,520,189	6,917678	6,574,384	6,415,235	6,311,743
Number of RX with daily MME>90	282,980	277,698	206,088	194,561	186,821
Opioid rate per patient's age range					
25-34	1,200	1,100	1,200	1,250	1,300
34-44	1,600	1,600	1,500	1,550	1,500
45-54	2,150	2,200	2,300	2,250	2,050
55-64	2,600	3,000	2,800	2,750	2,600
Opioid RX for male & female (ages 25-64)					
Females	4,030,000	4,200,000	4,300,000	4,350,000	4,250,000
Males	3,500,000	3,600,000	3,700,000	3,850,000	3,750,000

		Opioid deaths age range			
25-34	486	733	1031	967	1218
35-50	959	1486	1831	1733	1651
Above 50	1583	2140	2426	2463	2394

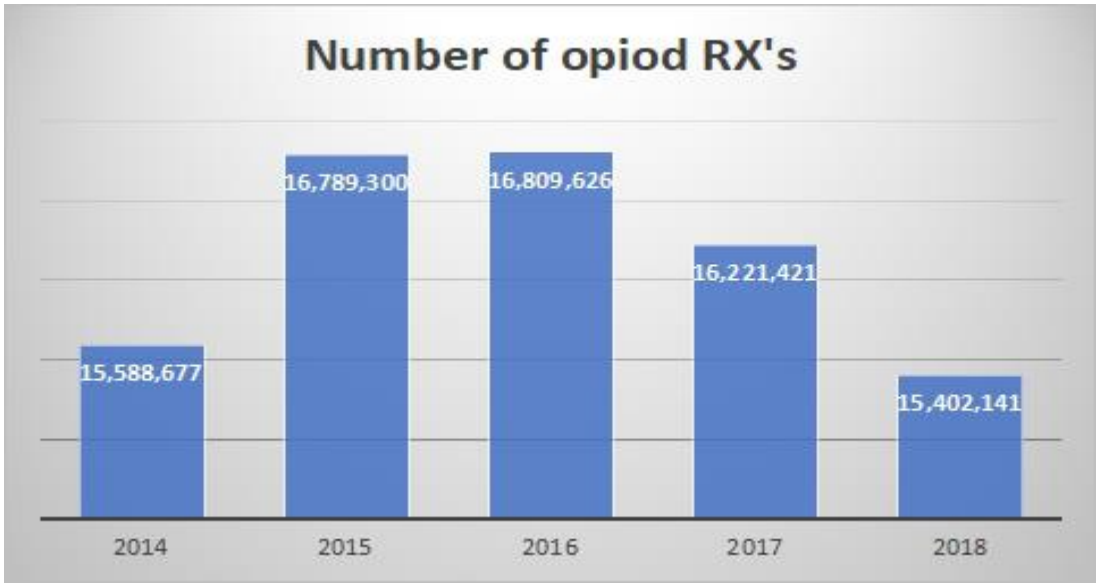
Explanation and Comparison of Variables-Florida

Total Number of Opioid Prescriptions

The total number of yearly opioid prescriptions peaked in 2016 and began to decline as shown in Figure 2.

Figure 2

Total Number of Yearly Prescriptions From 2014 to 2018, Florida

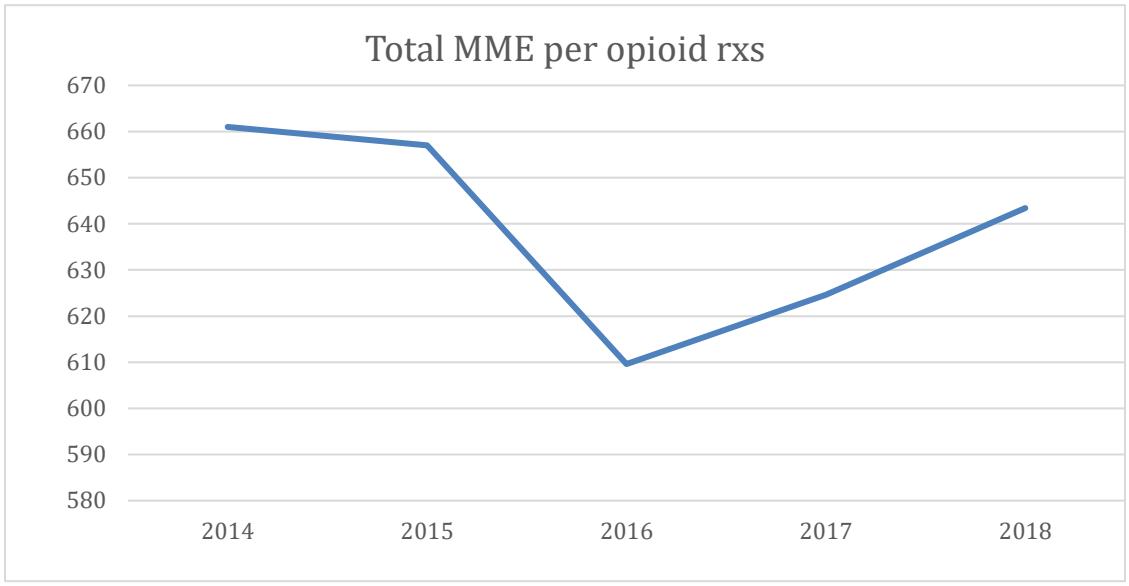


The Total Number of Morphine Milligram Equivalents (MME) per Opioid Prescription

The total number of MME per opioid prescription has been increasing gradually, which in turn increases the addictiveness of the opioid medication, as shown in Figure 3.

Figure 3

Total Morphine Milligram Equivalents (MME) per Opioid Prescription

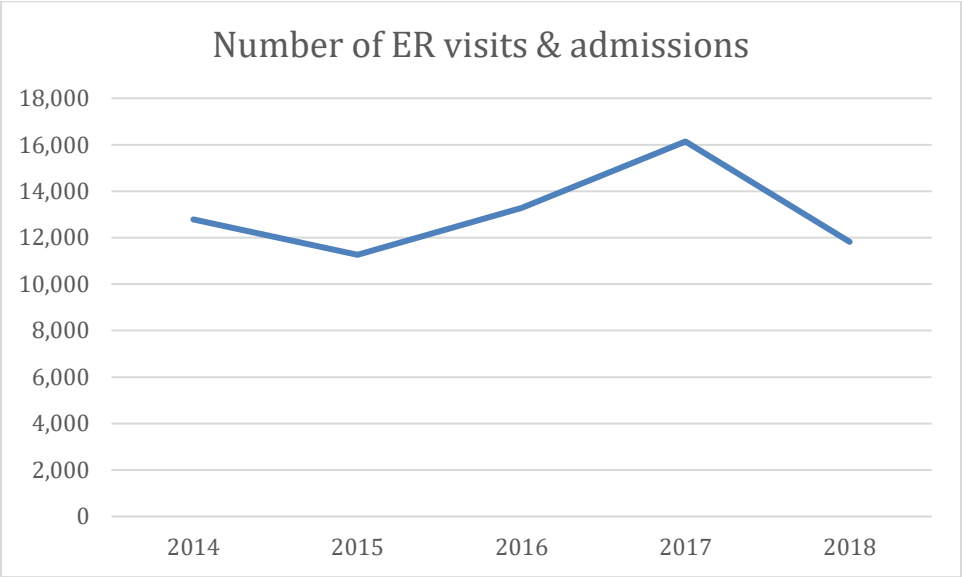


The Total Number of Emergency Room (ER) Visits and Admissions

The number of opioid-related ER visits and admissions increased from 2015 to 2017; however, the number began to decrease in 2018, as shown in Figure 4.

Figure 4

Total Number of Yearly ER Visits and Admissions From 2014 to 2018

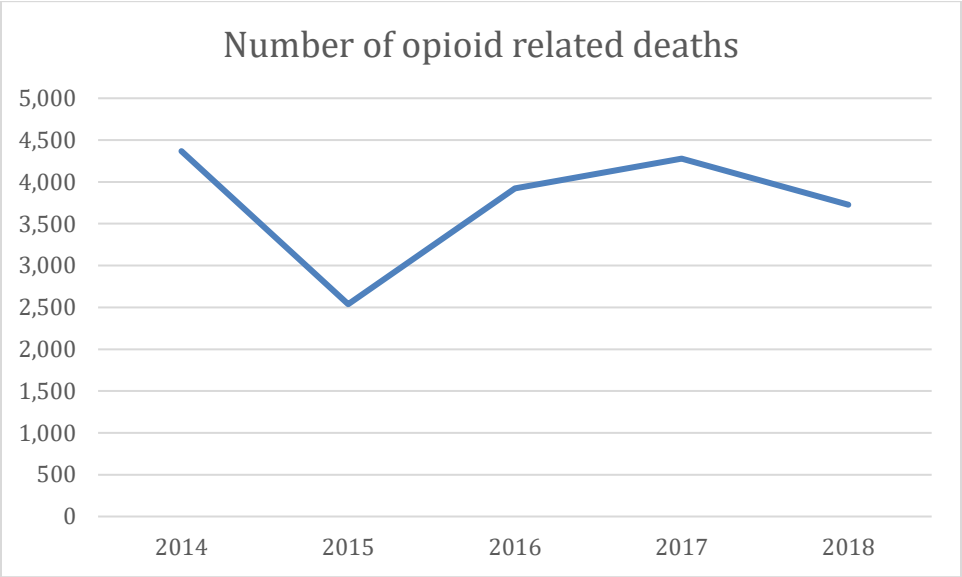


The Total Number of Opioid-Related Deaths

The number of opioid-related deaths almost doubled from 2,538 in 2015 to 4,280 in 2017. This is represented in Figure 5

Figure 5

Number of Yearly Opioid-Related Deaths from 2014 to 2018



Years

The Number of Healthcare Providers Trained in PDMP

The year 2015 had the highest number of trained healthcare providers, and there was a decrease in the following 2 years. However, the numbers went back up in 2018, as shown in Figure 6.

Figure 6

Number of Healthcare Providers Trained in PDMP

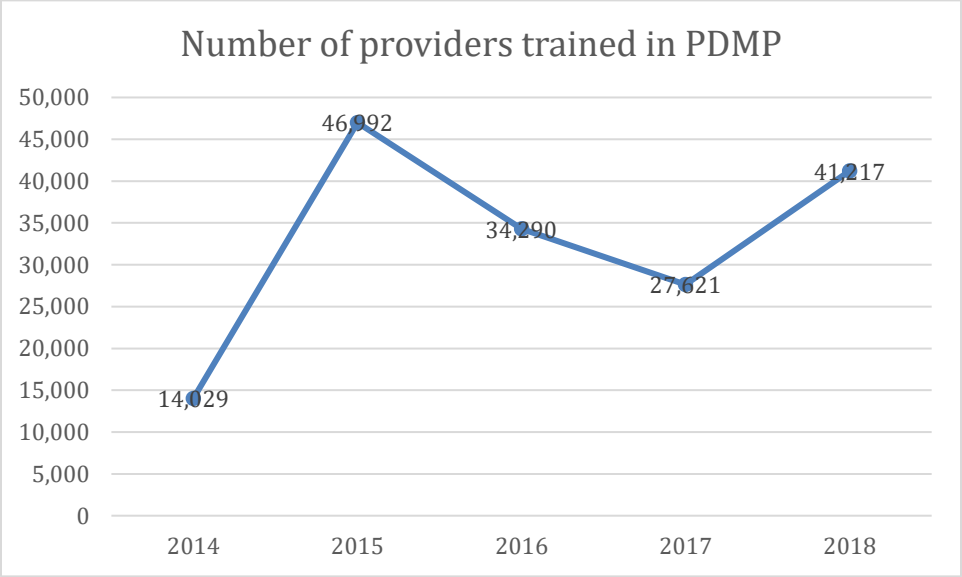


Figure 7

Number of Opioid Naïve Patients

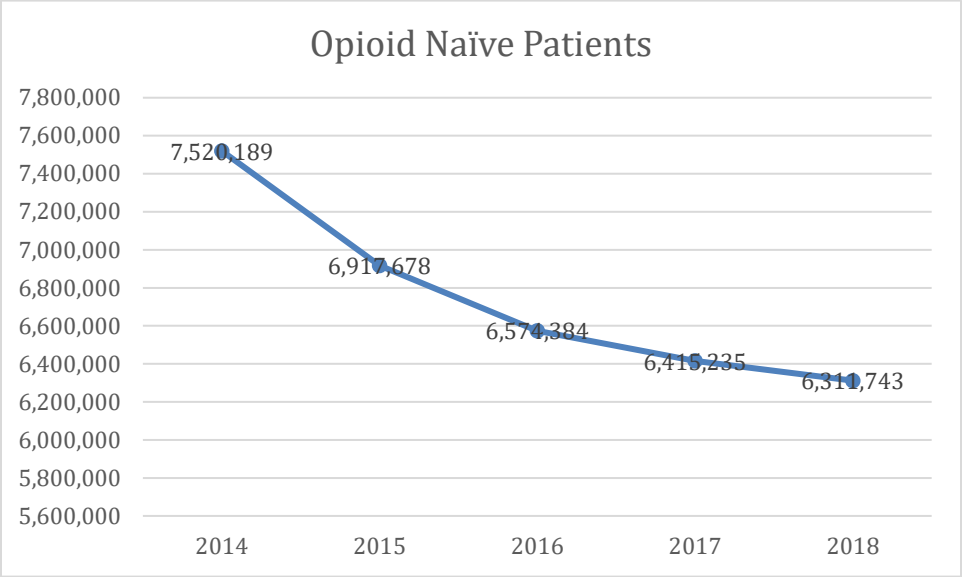
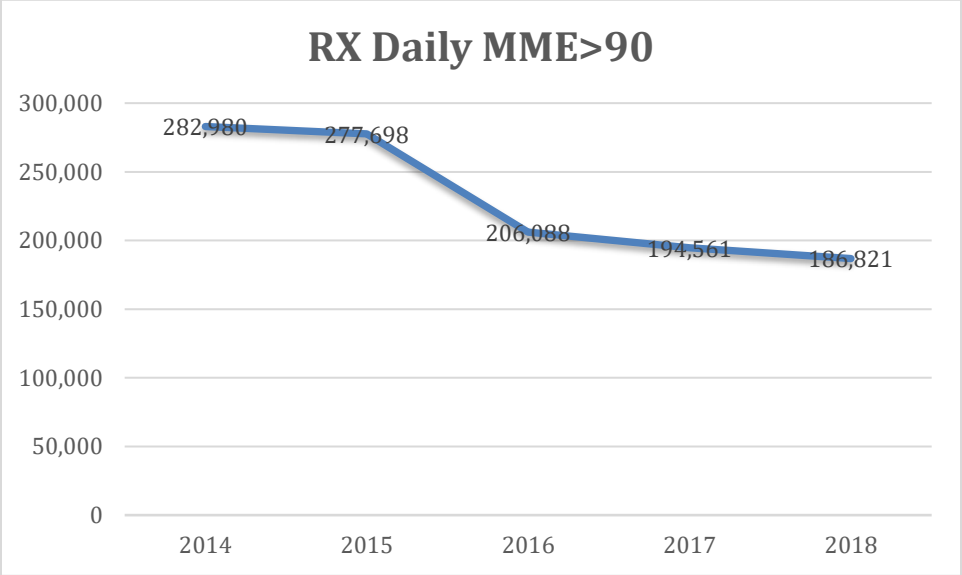


Figure 8

Number of Prescriptions with Daily MME>90

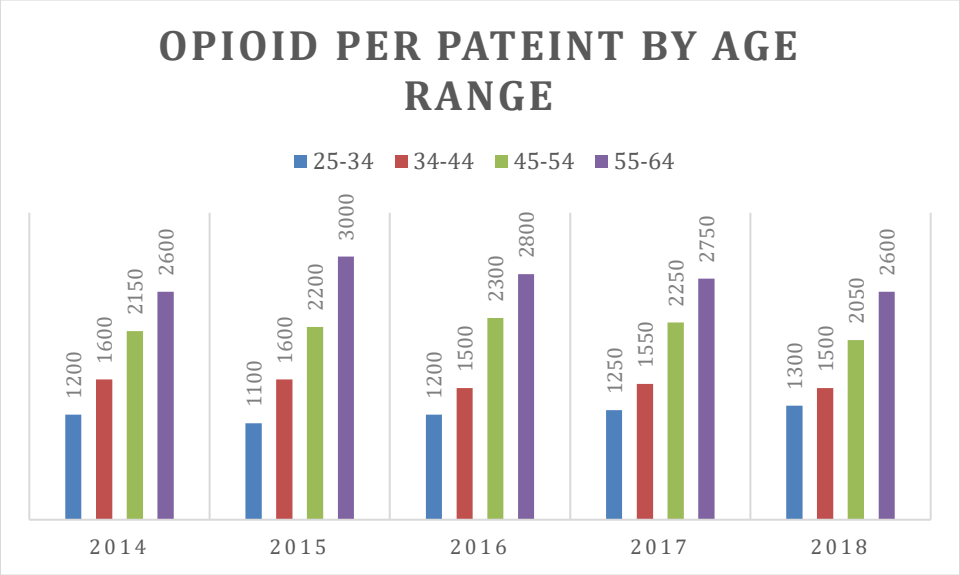


Opioid rate per patient age group

The opioid rate per 1,000 patient age group remained steady over the years, with the 55 64 age groups being the highest consumers as shown in Figure 3.8.

Figure 9

Opioid rate per patient age group

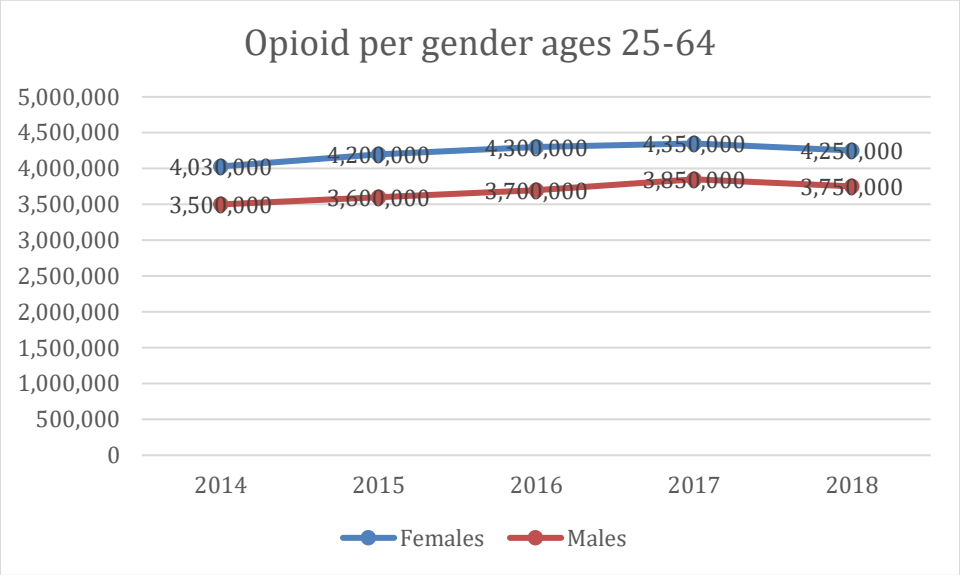


Total Number of Opioid prescription for Male and Female

The result shows that females consume more opioid prescriptions than males over the years.

Figure 10

Number of yearly opioid prescriptions per gender



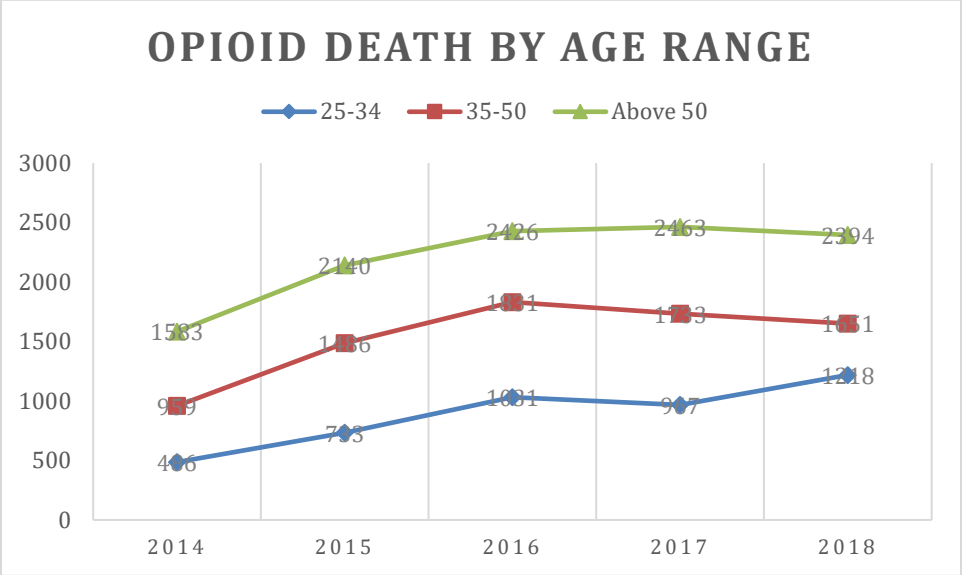
Years

Total Number of Opioid-related deaths by age group

The total number of opioid-related deaths are highest among people 50 and older over the years from 2014 to 2017.

Figure 11

Number of yearly opioid-related deaths by age group



Descriptive Demographics and Univariate Analysis of the Georgia Sample

The Georgia PDMP is also managed by the State's Department of Health. The available data collected were from the year 2014 to 2018. They include the total number of prescription opioids written per year; the number of Emergency Room visits & admissions from; the number of opioid-related deaths in the state; the number of opioid naïve patients (thus patients who have not had any opioid prescriptions in past 6 months or more); and the number of prescription opioids with a daily MME greater than 90.

Table 4

Georgia PDMP Data

Year	2014	2015	2016	2017	2018
Number of Opioid RX's	8,912,489	8,736,389	8,589,707	8,001,050	7,487,527
Number of ER visits & admissions	9,569	8,484	7,843	8,278	7,359
Number of RX with Daily MME>90	249,561	217,821	184,170	172,034	125,140
Number of Opioid Naïve Patients	320,189	311,743	298,402	224,297	217,359
Number of Opioid Related Deaths	1,304	1,268	954	1,051	876
Opioid Rate Per Patient's Age					
Range					
25-34	781,171	681,132	600,542	751,408	651,423
34-44	1,677,522	1,491,238	899,000	1,110,468	991,575
45-54	1,740,394	1,639,475	1,225,000	1,568,651	1,409,081
55-64	1,760,198	1,569,760	1,650,000	1,404,320	1,879,290
Opioid Per Gender & Age (25-64 years)					
Female	5,163,798	5,052,724	4,953,000	4,689,364	4,387,736

Male	4,352,101	4,211,484	3,705,000	3,304,324	3,094,257
			Opioid Deaths Age Range		
25-34	288	255	231	303	220
35-44	264	259	279	307	225
45-54	299	295	298	305	171
55-64	178	165	189	198	135

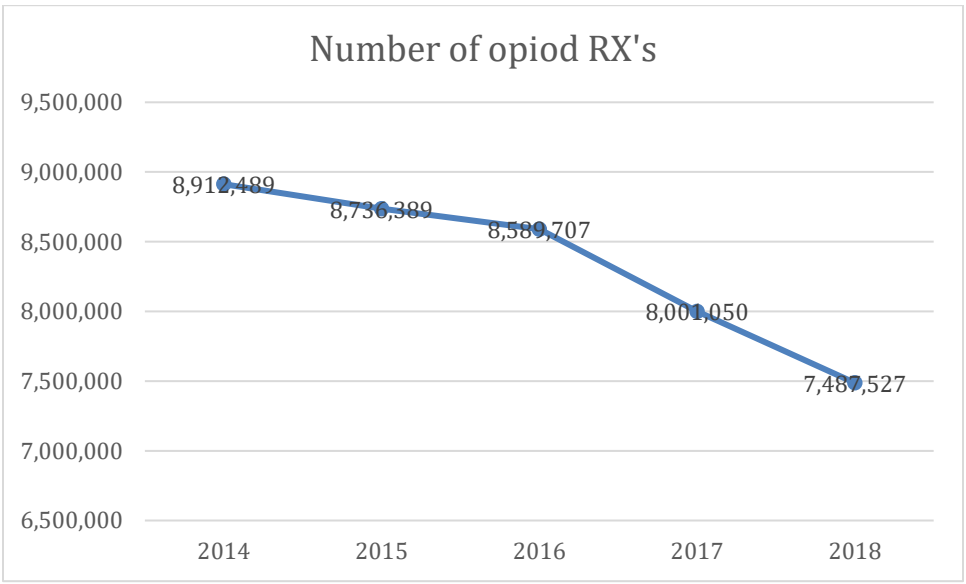
Explanation and Comparison of Variables-Georgia

Total Number of Opioid Prescriptions

The total number of opioid prescriptions dispensed to patients has been decreasing from 2014 to 2018 as shown in Figure 3.11.

Figure 12

Total number of opioid prescriptions, Georgia

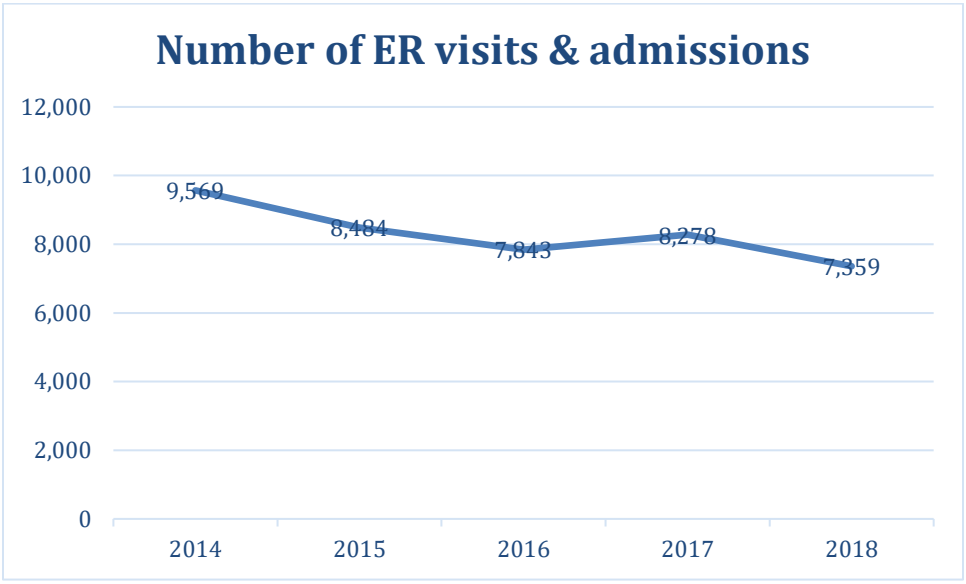


Total Number of ER Visits and Admissions

The number of ER visits and admissions peaked in 2017; however, it relatively reduced in 2018.

Figure 13

The number of Emergency Room visits and admissions, Georgia

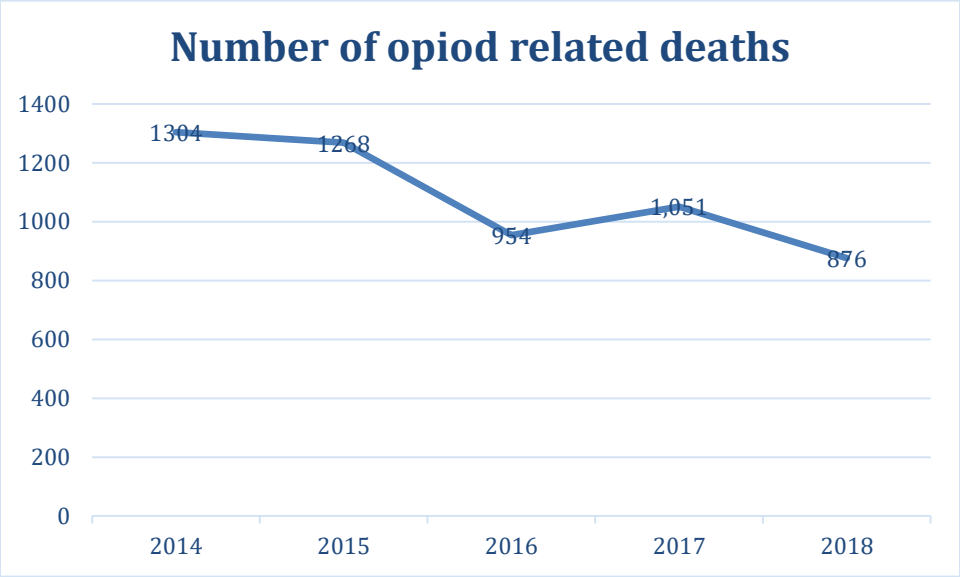


Total number of opioid-related deaths

The number of opioid-related deaths peaked in 2017 just as the number of ER visits and admissions and began to decrease.

Figure 14

Number of opioid-related Deaths, Georgia

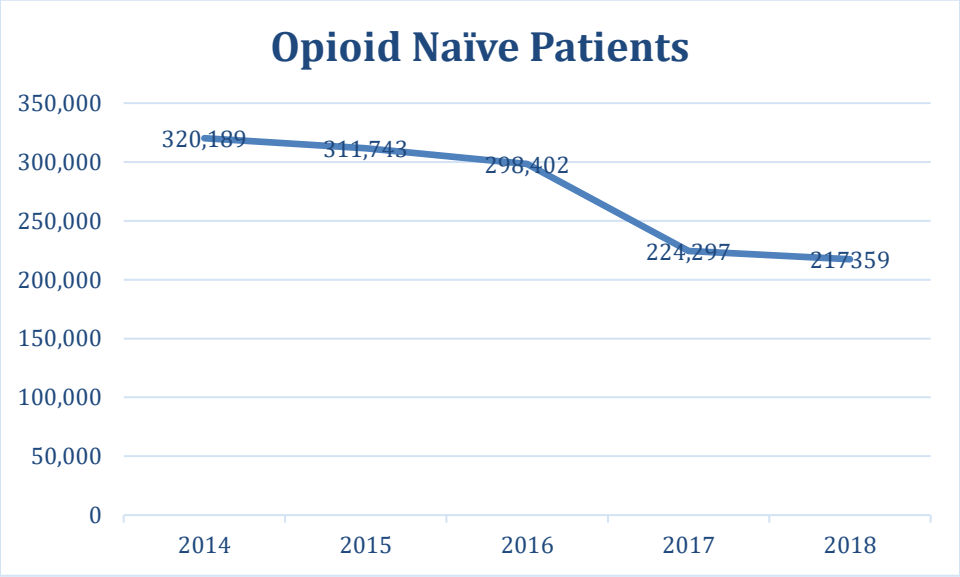


Total Number of opioid naïve patients

The total number of opioid naïve patients decreased over the years from 2014 to 2018.

Figure 15

Number of opioid naïve patients

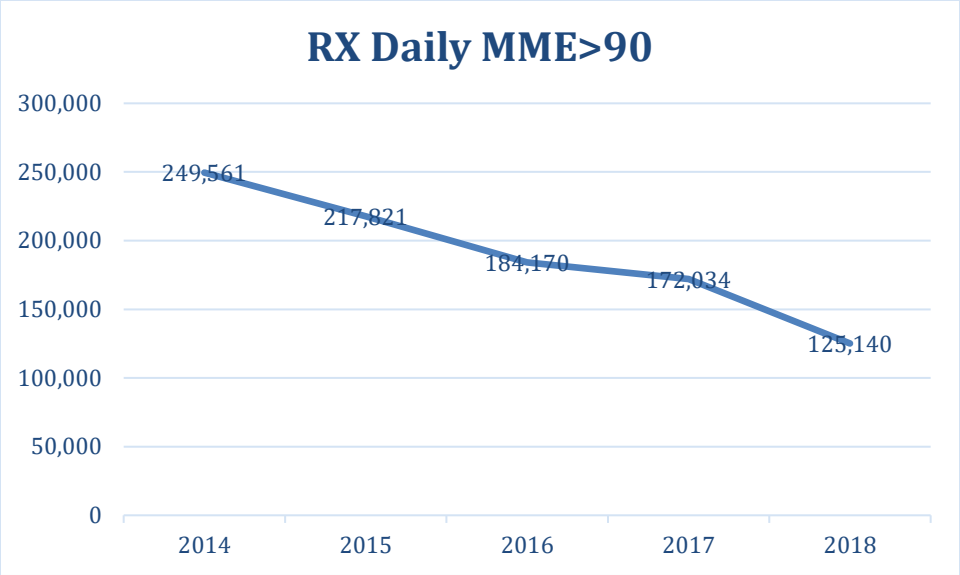


Total Number of Opioid Prescriptions with daily MME>90

The total number of prescriptions with daily MME>90 has been decreasing over the years from 2014 to 2018.

Figure 16

Number of opioid prescriptions with daily MME>90

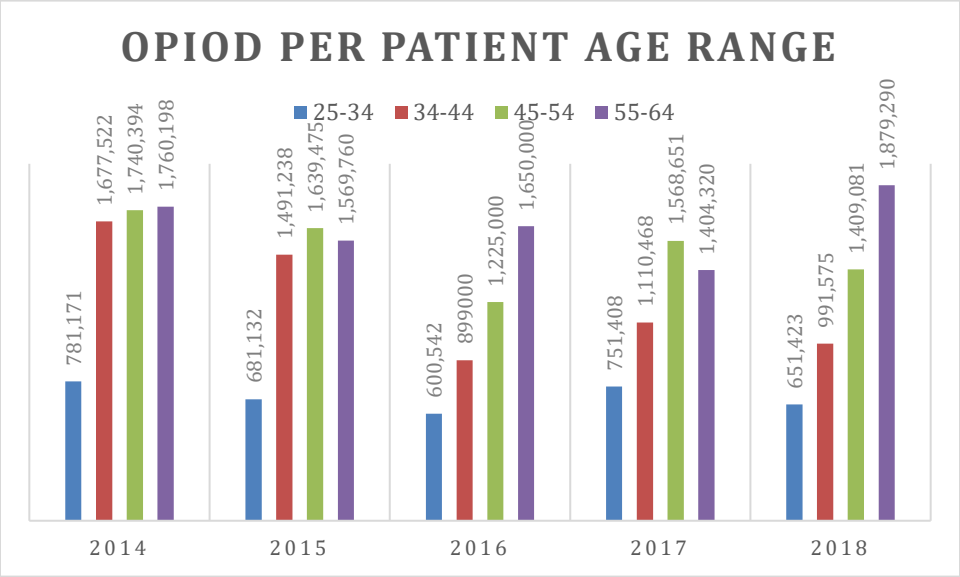


Opioid rate per Patient Age Group

The rate of opioid consumption among age groups between 45 to 54 years and 55 to 64 is among the highest from 2014 to 2018.

Figure 17

Opioid rate per patient's age groups

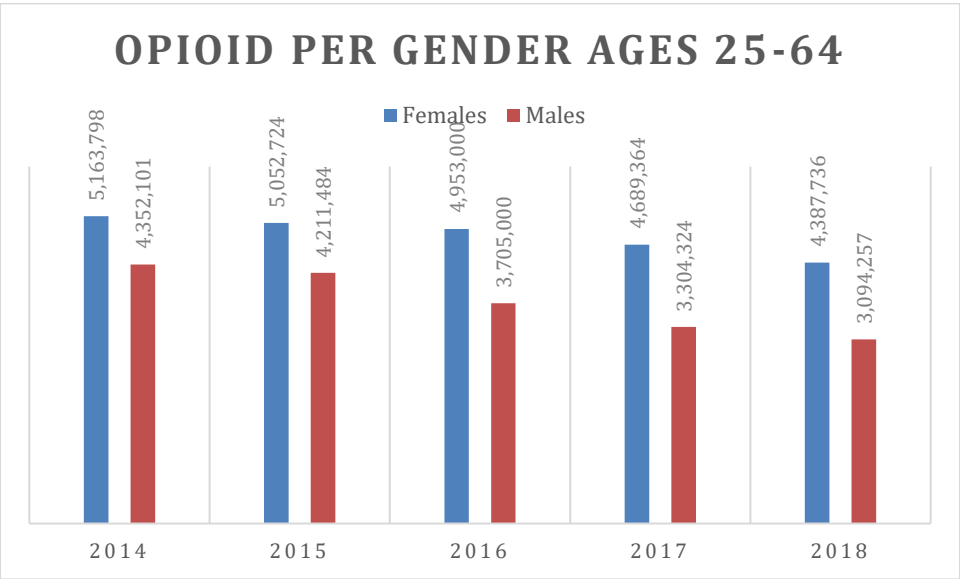


Prescription Opioid Consumption between Male and Female Ages 25-64 years

The data shows that females consume more opioid prescriptions than males in all the years compared as presented in Figure 3.17.

Figure 18

Opioid RX for male and female

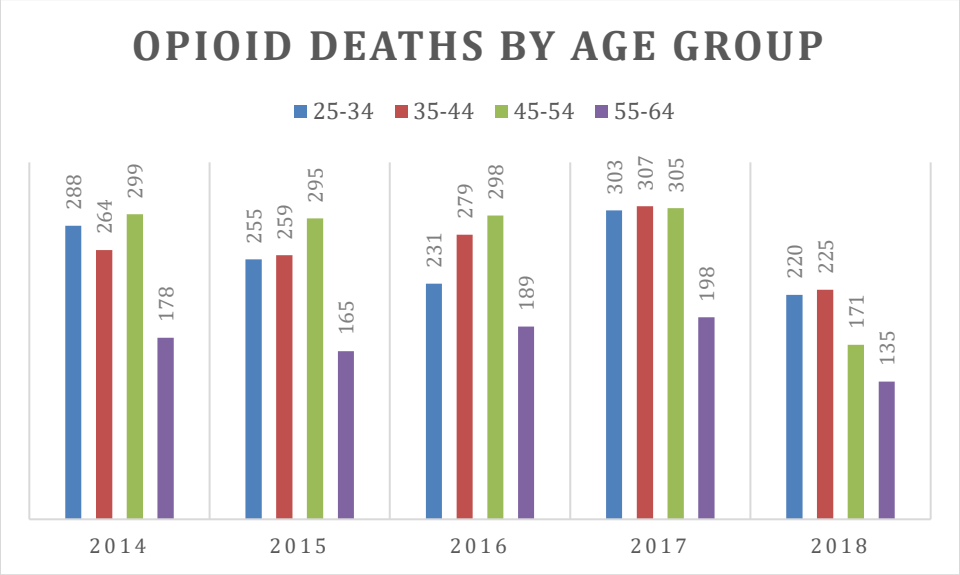


Total Number of Opioid-related Deaths per Age Groups

The total number of opioid deaths among age groups has been reducing over the years from 2014 to 2018. Furthermore, the data also shows that the ages between 35-44 and 45-54 have the highest mortality rates.

Figure 19

Number of opioid-related deaths per age group



Descriptive Statistics for Florida Data

The number of Trained Providers has a mean of 32829.80 (S.D 12783.26). The mean for the number of yearly Opioid Prescriptions is 16,162,233.0 (S.D 656227.91). The mean for Emergency Room Visits and Admissions per year is 13,058.6 (SD 1,895.13). The mean for Opioid-Related Deaths per year is 3,767.2 (SD 734.97). The mean for the MME per year is 638.52 (SD 22.82). The mean for Opioid Naïve Patients is 674,784.5 (SD 488,943.13). The mean for Prescription with daily MME >90 is 229,629.6 (SD 46,833.28) (See: Table 3.3).

Table 5

Descriptive Statistics for Florida

	Mean	Std Deviation	Std Error
Year Prescriptions	16,162,233	656,227.91	293,474.04
Trained Providers	32,829.8	12,783.26	5,716.85
Emergency Room visits	13,058.6	1,895.13	847.53
Opioid-Related Deaths	3,767.2	734.97	328.69
MME per Opioid RX's	638.52	22.82	10.21
Opioid Naïve patients	674,784.8	488,943.14	21,8662.02
RX Daily MME>90	229,629.6	46,833.28	20,944.48

To test the null hypothesis for the Research Questions 1 to 3 which states that there is no association between the number of state-sponsored PDMPs trained healthcare providers and the number of opioid overdoses, the number of opioid admissions and the number of opioid-related deaths a one-way ANOVA (Analysis of Variance) was conducted using SPSS software version 21 and post-hoc test using the Tukey HSD to evaluate pairwise differences between means of the variables. The results from the ANOVA analysis revealed a significant difference in the mean of trained providers with $F(6, 28) = 1996.172127.68$, $p<.001$.

Table 6

One-way ANOVA for Florida Data

Source	Sum of Squares	Df	Mean Square	F	Sig
Between groups	1149900086613551.8	6	191650014435591.97	1996.172	.000
Within groups	2688245461020.12	28	96008766465.01		
Total	1152588332074572.0	34			

In accordance with the post-hoc tests, it is notable that there are significant differences within the variables. There is a significant difference between the mean of the number of trained providers and the mean of the number of yearly prescriptions (mean difference=16,129,403.20) with 95% C.I (15,507,766.81, 16,751,039.59). There is a significant difference between the mean of the number of yearly prescriptions and the mean of the number of emergency room visits and admissions (mean difference=16,149,174.4) with 95% C. I (15,527,538.0, 16,770,810.79).

There is a significant difference between the mean of the number of yearly prescriptions and the mean of the number of opioid-related deaths (mean difference=16,158,465.8) with 95% CI (Confidence Interval) (15,536,829.4, 16,780,102.19). There is also a significant difference between the mean of the number of yearly prescriptions and the mean of the number of prescriptions with MME>90) (mean difference= 16,161,594.48) with 95% CI (15.539, 958.09, 16,783,230.87).

There is also a significant difference between the number of yearly prescription and opioid naïve patients (mean difference=9,414,387.2) with 95% CI (8,792,750.81, 10,036,023.59). There is a significant difference between the number of yearly prescription

and the number of prescription with Daily MME>90 (mean difference=15,932,603.4) with 95% CI (15,310,967.01, 16,554,239.79). There is a significant difference between the mean of the number of trained providers and the mean of the number of emergency room visits and admission (mean difference=19,771.2) with 955 CI (-601,865.19, 641,407).

There is a significant difference between the mean of the number of trained providers and the mean of the number of opioid-related deaths (mean difference=29,062.60) with 95% CI (-592573.79, 650,698.99). There is a significant difference between the mean of the number of trained providers and the mean of the number of prescriptions with Morphine Milligram Equivalence>90) (mean difference=32,191.28 with 95% C I (-589,445.11, 653,827).

There is a significant difference between the mean of the number of trained providers and the mean number of opioid naïve patients (mean difference=6,715,016.00) with 95% CI (7,336,652.39, -6,093,379.61). There is a significant difference between the mean of the number of trained providers and the mean of the number of prescription with Daily MME>90 (mean difference= 196,799.80) with 95% CI (-818,436.19, 424,836.59).

There is a significant difference between the mean of the number of emergency room visits and admissions and the mean of the number of Opioid-related deaths (mean difference=9,291.40) with 95% CI (-641,407.59, 601,865.19). There is a significant difference between the mean of the number of emergency room visits and admissions and the mean of the number of prescriptions with MME>90 (mean difference=12501.6) with 95% CI (-786869.6, 811872.9) (mean difference=12,420.08) with 95% CI (-609,216.31, 634,056.47). There is a significant difference between the mean of the number of

emergency room visits and admissions and the mean of the number of opioid naïve patient (mean difference= 6,734,787.20) with 95% C.I (-7,356,423.59, -6,122,442.21).

There is a significant difference between the mean of the number of emergency room visits and admissions and the mean of the number of prescription with Daily MME> 90 (mean difference= 216571.00) with 95% CI (-838207.39, 405,065.39). There is a significant difference between the mean of the number of Opioid-related Deaths and the mean of the number of prescriptions with MME>90 (mean difference=3128.68) with 95% CI (-618,507.71, 624,765.07).

There is a significant difference between the mean of the number of Opioid-related Deaths and the mean of the number of opioid naïve patients (mean difference= 6,744,078.60 with 95% CI (-73,65,714.99, -6,122,442.21).

There is a significant difference between the mean of the number of Opioid-related Deaths and the mean of the number of prescriptions with Daily MME > 90 (mean difference=225,862.40) with 95% CI (-847,498.79, 395,773.99). There is a significant difference between the means of the MME per Prescription and the mean of the number of opioid naïve patients (mean difference=6,747,207.28) with 95% CI (-7,368,843.67, -5656759.7880). There is a significant difference between the means of the MME per Prescription and the mean of the number of prescriptions with Daily MME>90 (mean difference=22,899.80 with 95% CI (-850,627.47, 39,245.31). There is a significant difference between the mean of the number of opioid naïve patients and the mean of the number of prescriptions with daily MME >90 (mean difference= 6,518,216.20) with 95% CI (5,896,579.81, 7,139,852.59). This is presented in Table 3.5 below.

Table 7

Pairwise Differences in Mean and Corresponding 95% Confidence Intervals-Florida data

	Trained Providers	Emergency Room visits	Opioid-Related Deaths	MME per Opioid RX	Opioid Naïve Patients	RX Daily MME>90
Yearly Prescriptions	16,129,403.20 (15,507,766.81, 16,751,039.59)	16,149,174.4 (15,527,538.0, 16,770,810.79)	16,158,465.8 (15,536,829.4, 16,780,102.19	16,161,594.48 (15.539,958.09 16,783,230.87)	9,414,387.2 (8,792,750.81, 10,036,023.59)	15,932,603.4 (15,310,967.01, 16,554,239.79)
Trained providers		19,771.2 (-601,865.19, 641,407)	29,062.60 (-592573.79, 650,698.99)	32,191.28 (-589,445.11, 653,827)	-6,715,016.00 (7,336,652.39, -6,093,379.61)	-196,799.80 (-818,436.19, 424,836.59)
Emergency Room Visits			9,291.40 (-641,407.59, 601,865.19)	12,420.08 (-609,216.31, 634,056.47)	-6,734,787.20 (-7,356,423.59, -6,122,442.21)	-216571.00 (-838207.39, 405,065.39)
Opioid-Related Deaths				3128.68 (-618,507.71, 624,765.07)	-6,744,078.60 (-73,65,714.99, -6,122,442.21)	-225,862.40 (-847,498.79, 395,773.99
MME PER Opioid RX					-6,747,207.28 (-7,368,843.67, -5656759.7880	-22,899.80 (-850,627.47, 39,245.31)
Opioid Naïve patients						6,518,216.20 (5,896,579.81, 7,139,852.59)
RX Daily MME>90						

*. The mean difference is significant at the 0.05 level

Descriptive Statistics for Georgia Data

The yearly prescription opioid has a mean of 8026094.7 (S.D 551516.6). emergency room admissions and visits have a mean of 7826.7 (S.D 459.7). The number of Opioid-related deaths has a mean of 960.3 (S.D 87.7). The number of Opioid Naïve patients has a mean of 246686.0 (S.D 44921.5) and the number of prescriptions with Daily MME>90 has a mean of 160448.0 (S.D 31173.9) as shown on Table 3.6 below.

Table 8

Descriptive statistics for Georgia-Data

	Mean	Std Deviation	Std Error
Number of Opioid RX's	8,345,432.40	589,209.48	263,502.49
Number of ER visits & admissions	8,306.60	827.47	370.06
RX Daily MME>90	189,745.20	47,129.56	21,076.98
Number of Opioid Naïve Patients	274,398.00	49,576.24	22,171.17
Number of Opioid Related Deaths	1,090.60	189.27	84.64

To test the null hypothesis for the Research Questions 4 to 6 which states that there is no association between community-based naloxone distribution (number of opioid prescriptions written and dispensed; the number of opioid prescriptions with MME above 90; the number of opioid-naïve patients (thus patients who never used prescription opioids in six months or more); the number of reported opioid overdoses; the number of addiction treatments admissions; and the number of Opioid-related deaths, a one-way ANOVA was conducted using SPSS software version 21 and post-hoc test using the Tukey HSD to evaluate pairwise differences between means of the variables of the Georgia Data. The results from the ANOVA revealed a significant difference in the mean of the variables with $F(4, 10) = 613.5$ $p<.001$. See Table 3.7 below for details.

Table 9

One-way ANOVA for Georgia Data

Source	Sum of Squares	Df	Mean Square	F	Sig
Between Groups	271013766929403.75	4	67753441732350.94	962.824	.000
Within Groups	1407390122022.40	20	70369506101.12		
Total	272421157051426.16	24			

Based on the post-hoc tests conducted, there is a significant difference between the mean of the number of Prescription opioids per year and the mean of Emergency room visits and admissions (mean difference= 8,337,125.80) with 95% C.I (7,835,085.93, 8,839,165.67). There is a significant difference between the mean of the number of prescription Opioids per year and the mean of the number of prescriptions with Daily MME>90 (mean difference= 8,155,687.20) with 95% C.I (7,653,647.33, 8,657,727.07). There is a significant difference between the mean of the number of prescription opioids per year and the mean of the number of Opioid Naïve Patients (mean difference= 8,071,034.40) with 95% C.I (7,568,994.53, 8,573,074.27).

There is a significant difference between the mean of the number of prescription opioids per year and the mean of the number of Opioid-related deaths (mean difference= 8,344,341.80) with 95% C.I (7,842,301.93, 8,846,381.67). There is a significant difference between the mean of the number of Emergency room admissions and visits and the mean of the number of Prescription Opioid with Daily MME>90 (mean difference= -181438.60) with 95% CI (-683,478.47, 320,601.27). There is a significant difference between the mean of the number of Emergency room admissions and visits and the mean of the number of Opioid Naïve Patients (mean difference -266091.40) with 95% CI (-768131.27, 235948.47).

There is a significant difference between the mean of the number of emergency room admissions and visits and the mean of the number of Opioid-related Deaths (mean difference= 7216.00) with 95% CI (-494823.87, 509255.87). There is a significant difference between the mean of the number of Prescriptions with Daily MME>90 and the mean of Opioid Naïve Patients (mean difference= -84652.80) with 95% C.I (-586692.67 - 417387.07). There is a significant difference between the mean of the number of Prescriptions with Daily MME>90 and the mean of the number of Opioid-related deaths (mean difference 188654.60) with 95% CI (-313385.27, 690694.47). There is a significant difference between the mean on the number of Opioid Naïve patients and the mean of the number of Opioid-related deaths (mean difference = 273307.40) with 95% C I (-228732.47, 775347.27). See Table 3.8 for details.

Table 10

Pairwise Differences in Mean and Corresponding 95% Confidence Intervals for Georgia Data

	Number of ER visits & admissions	RX Daily MME>90	Number of Opioid Naïve Patients	Number of Opioid-Related Deaths
Number of Opioid RX's per year	8,337,125.80 (7,835,085.93, 8,839,165.67)	8155687.20 (7,653,647.33, 8,657,727.07)	8071034.40 (7,568,994.53, 8,573,074.27)	8,344,341.80 (7,842,301.93, 8,846,381.67)
Number of ER visits & admissions		-181438.60 (-683,478.47, 320,601.27)	-266091.40 (-768131.27, 235948.47)	7216.00 (-494823.87, 509255.87)
RX Daily MME>90			-84652.80 (-586692.67, -417387.07)	188654.60 (-313385.27, 690694.47
Number of Opioid Naïve Patients				273307.40 (-228732.47, 775347.27)
Number of Opioid-Related Deaths				

Table 11

Multiple Linear Regression, Florida Data

	Model Summary									
						Change Statistics				
Mode	R	R Square	Adjusted R Square	Std Error of Estimate	R Square Change	F Change	df1	df2	Sig F Change	Durbin-Watson
1	1.000[a]	1.000			1.000		4	0		1.833

Multiple linear regression test was performed to determine the influence of the various independent variables on the dependent variable (The number of trained providers in the PDMP per year from 2014 to 2018). From the above table, the R square value is 1.000. This shows the predictor values such as the number of prescriptions with daily MME>90 from 2014 to 2018; the number of opioid prescriptions per year from 2014 to 2018 in Florida; the number of ER visits and admissions per year from 2014 to 2018 in Florida; and the number of opioid-related deaths per year from 2014 to 2018 in Florida has a significant influence on the number of trained providers in the PDMP. The Durbin-Watson value of 1.833 is a health assumption that first-order linear auto-correction is nonexistent in the multiple linear regression performed.

Table 12

Multiple Linear Regression, Georgia Data

Model Summary										
					Change Statistics					
Mode	R	R Square	Adjusted R Square	Std Error of Estimate	R Square Change	F Change	df1	df2	Sig F Change	Durbin-Watson
1	1.000[a]	1.000			1.000		4	0		1.703

Multiple linear regression test was also performed to determine the influence of the various independent variables on the dependent variable (the number of opioid prescriptions per year from 2014 to 2018). From the above table, the R square value is 1.000. This shows the predictor values such as the number of Opioid prescriptions with Daily MME>90 per year from 2014 to 2018; the number of Opioid naive patients (thus patients who have never used prescription opioids or haven't used it in the past 6 months

or more); the total number of Opioid-related deaths from 2014 to 2018 in Georgia; the total number of ER visits and admissions per year from 2014 to 2018 in Georgia has a significant influence on the number of opioid prescriptions per year from 2014 to 2018 in Georgia.

The Durbin-Watson value at 1.000 means that first-order linear auto-correlation are nonexistent in the multiple linear regression performed.

Analysis of Research Questions

Research Question One

RQ1: Is there an association between the number of state-sponsored PDMPs trained healthcare providers per year and the number of reported opioid overdoses per year among adults 25 to 64 years?

Research Question Two

RQ2: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of opioid addiction treatment admissions per year among adults 25 to 64 years?

Research Question Three

RQ3: Is there an association between the number of state-sponsored PDMPs trained healthcare providers and the number of deaths attributed to opioid overdose-related deaths per year among adults 25 to 64 years?

From the One-way ANOVA and the post-hoc analysis of the Florida data, it can be said that the null hypothesis for Research Questions One to Three are false and that there are significant differences between the mean of the variables. Research shows that prescription opioid optimum therapeutic daily MME range is between 50 and 90 milligrams. Ranges above 90 milligrams have a high risk of overdose (Chua et al., 2020).

Research Question Four

RQ4: Is there an association between community-based naloxone distribution and the number of reported opioid overdoses per year among adults 25 to 64 years?

Research Question Five

RQ5: Is there an association between community-based naloxone distribution and the number of opioid addiction treatment admissions per year among adults 25 to 64 years?

Research Question Six

RQ6: Is there an association between community-based naloxone distribution and the number of deaths attributed to opioid misuse/overdose per year among adults 25 to 64 years?

From the One-way ANOVA and the post-hoc analysis of the Georgia data, it can be deduced that the null hypothesis for Research Questions Four to Six are also false and that there are significant differences between the mean of the variables. According to Behar et al. (2016) and Coffin et al. (2016), naloxone co-prescribing with prescription opioids is associated with a reduction in opioid-related ER visits. Research also shows that the implementation of the national opioid overdose and Naloxone Distribution (OEND) has reduced the number of addiction treatment, hospital visits, and opioid-related mortality

(Oliva et al., 2017). Furthermore, the distribution of naloxone kits in pharmacies and hospitals per to state's Public Health directors standing orders and protocols to allow non-patient specific dispensing of naloxone have reduced opioid-related deaths (Bachyrycz et al., 2018).

Summary

This research has demonstrated that the introduction of PDMPs and the Surgeon Generals standing orders on Naloxone dispensing has had some effects on the considered variables over the years compared. The introduction of the standard order prescription by the Surgeon General in both states could contribute to the decline in ER visits and admissions and the decline in opioid-related deaths in Georgia. However, the rise in opioid-related deaths in Florida could be due to other confounding factors. The significance of these results and how they can be applied towards positive social change would be discussed in the next chapter.

Section 4: Application to Professional Practice and Implications for Social Change

Introduction

The misuse of prescription opioids, including abuse, dependence, and overdose, is well documented. According to the 2014 National Survey on Drug Use and Health, 15 million people aged 12 or older used prescription drugs non-medically in the past year. In 2013, there were 16,235 deaths from prescription opioid overdose. In 2014, the CDC declared drug overdose deaths an epidemic (Florence et al., 2016; Kandel et al., 2017). The opioid crisis has also resulted in a substantial cost burden to many communities and states. The health care costs, criminal justice expenses, and productivity losses attributable to opioid misuse were estimated to a total amount of $78.5 billion in 2014 alone (Chen et al., 2019).

In this study, I compared the state-sponsored PDMP data for Florida and Georgia. The variables were the number of opioid prescriptions written each year, the number of opioid prescriptions with MME above 90 each year, the number of opioid naïve patients (patients who have never used opioid prescriptions or have not used it in the last 6 calendar months), the number of healthcare providers trained to use the PDMP, the number of opioid-related emergency room visits and admissions each year, the number of related opioid admissions into treatment centers each year, the number of opioid-related deaths each year, and the gender and age of patients (age range between 25 and 64 years). I found that most of the data for the variables correspond to both states.

Socio-Ecological Model Theory

The SEM suggests that an individual's behavior is integrated into a dynamic network of intrapersonal characteristics, interpersonal processes, institutional factors, community features, and public policy. The model stipulates that interactions between individuals and their environment are reciprocal, implying that the individual is influenced by their environment and the environment is influenced by the individual.

The SEM further assumes that the environment is comprised of different overlapping levels. The intrapersonal level encompasses the research participant's knowledge, awareness, attitudes, beliefs, and perceptions. The individual's family, friends, and healthcare providers are important components of the interpersonal level. The healthcare institution's rules, regulations, and general attitude toward research comprise the institutional level.

The community level includes local cultural attitudes, availability of public amenities such as transportation, and safety of the neighborhood. The public policy level includes local, state, and federal laws regarding socio-behavior. The SEM takes into account socio-cultural factors, as well as environmental factors, and their linkages to biologic factors.

Interpretation of the Findings

From the study on RQ1, I found that almost all the null hypotheses to research questions were not valid, while the alternate hypothesis was right. There was however an association between the state-sponsored PDMP trained healthcare providers and the number of reported opioid overdoses among adults 25 to 64 years. It could be seen that in

Florida as well the total number of prescription opioids dispensed decreased over the years from 2014 to 2018. Also, in Georgia, the total number of prescription opioids with a daily MME>90 decreased over the years.

On RQ2, the data shows that there is an association between the number of state-sponsored PDMPs trained healthcare providers per year, the number of opioid addiction treatment admissions, and the number of ER visits and admissions among adults 25 to 64 years (controlled for age group and gender). On RQ2, there was a relationship between the PDMPs and the number of opioid addiction treatment admissions. The data showed that the total number of ER visits and hospitalizations decreased between 2017 and 2018.

RQ3 only showed an association between the PDMP and deaths attributed to opioid misuse/overdose in Georgia. The total number of opioid-related deaths decreased between 2017 and 2018, as did opioid-related deaths by age range. In Florida, however, the total number of opioid-related deaths increased between 2017 and 2018. This could be due to the high incidence of illicit drugs such as synthetic fentanyl in the state.

RQ4 to RQ6 showed that the ready availability and accessibility of naloxone through state health department standing order, and the ability of non-patients to purchase naloxone without a prescription decreased the total number of opioid overdoses, which reflects in the reduction of ER visits and admission as well as the number of opioid-related deaths over the period.

Limitations of the Study

Florida started collecting public health data for its PDMP around 2012. However, Georgia only began to collect data in 2014. Comparing two state-sponsored programs

with different duration of implementation made the data analysis difficult. The Florida health department has all data available to the general public, while the Georgia health department requires Institutional Review Board application, which caused a delay in the data gathering process.

Recommendation

Future research could include multiple states with varying demographics and locations. Standardization of data reporting and regulations to all state-sponsored PDMPs could influence any comparison research. From this current study, it was revealed that there is a need for states to implement uniform and consistent public health policies and guidelines across board to prevent cross-border travel to and from states with relaxed policies.The licensure and continuing education requirements for healthcare providers on prescribing prescription opioids should be adequate and extensive (Glowacki, 2015; Lewis et al., 2015).

Implications for Professional Practice

Education and training of healthcare providers on prescription opioid prescribing guidelines, proper medication, disposal systems, patient screening, doctor's office urine test, addiction treatment, and proper patient referral processes should be incorporated as tools for the control and reduction of prescription opioid abuse/overdose. Furthermore, appropriate policies and practices to prevent an increase in illicit opioid drug use such as synthetic fentanyl and heroin could reduce opioid-related deaths in general (Hagemeier et al., 2018; Stratton et al., 2018).

Research has proven that opioid addiction has heritability rates similar to other chronic diseases such as diabetes, asthma, and hypertension (Volkow & Mclellan, 2016). Prescription opioid abuse is significantly affected by the lack of structural and social determinants of health in the United States public health system. Healthcare providers are either undereducated or misinformed about the appropriate use of prescription opioids for non-cancer pain management and treatment (Dasgupta et al., 2018; Stratton et al., 2018). Therefore, the need for comprehensive education along such lines is paramount.

Collaboration between healthcare providers to improve trustworthiness as well as the use of the lowest effective for the shortest effective duration to achieve the appropriate pain management would reduce prescription opioid abuse and reduce addiction treatment cases (Volkow & Mclellan, 2016). The influence of the big drug manufacturing companies on both state and federal authorities through lobbying and funding of advocate group to push false narratives on non-cancer pain management has contributed significantly to this prescription opioid epidemic (Stratton et al., 2018).

Social Change

Prescription opioid abuse has a disproportionately high prevalence among non-metropolitan, suburban, and rural area populations due to the increased availability and accessibility of prescription opioids by the older population. These medications have become easily accessible to young family members who tend to abuse them (Faryar et al., 2018). PDMPs, education of healthcare providers, and community use of naloxone and practice guidelines have reduced misuse, abuse, addiction, diversion, and false acquisition of prescription opioids (Pitt, Humphreys & Brandeau, 2018) There is a need

for effective public health education using social media, print media, and the internet on the effects of prescription opioid abuse/overdose on the population.

Lack of economic opportunities, poor working conditions, depression, hopelessness, and lack of social capital are significant contributors to prescription opioid abuse in many American communities (Dasgupta et al., 2018). The public health issue of opioid abuse should be solved holistically with all social health determinants considered. Pharmaceutical companies need to be tightly regulated and focused on their labeling, post-marketing surveillance, abuse-deterrent formulations, and use of non-opioid alternatives for non-cancer pain management.

Methods of overdose and addiction treatments as well use of counselors should be reviewed continuously by the state PDMPs and public health authorities. Unfortunately, recent research shows that the number of opioid prescriptions written in the United States is roughly equal to the number of the adult population (Califf et al., 2016). The management of non-cancer pain with cognitive behavioral therapy as well as a complementary alternate medicine should be considered (Salas et al., 2016).

Conclusion

This research has demonstrated that the use of state-sponsored PDMPs, availability and accessibility of naloxone, healthcare provider education, patient screening, and abuse-deterrent formulations have a significant role in the reduction and prevention of prescription opioid overdose among the population, especially those between the ages of 25 and 64 years.

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