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Impact of Kentucky's Prescription Drug Monitoring Program on Opioid Overdose Fatality Rates

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Abstract

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MS, University of Louisville, 2015

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Doctoral Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Over the last 7 years, there has been an alarming increase in the number of opioid overdose fatalities in Jefferson County, Kentucky. The increase has occurred despite Kentucky's passage of a prescription drug monitoring program (PDMP) as defined by House Bill 1 (HB1) in 2012. Following the passage of Kentucky's PDMP, heroin and fentanyl surpassed other prescription drugs as the most identified drugs in overdose deaths in Kentucky. Little is known about how the implementation of a PDMP influences the overall opioid overdose fatality rate. The purpose of this quantitative research, using a quasi-experimental design, was to evaluate the relationship between the implementation of Kentucky's PDMP and a documented rise in heroin and fentanyl overdose fatalities. Rational choice theory was the theoretical framework for this study. Data regarding prescribing rates and opioid mortality rates were collected from an online database published by the Centers for Disease Control. Interrupted time-series analyses were used to analyze the data. Regarding prescription opioids, heroin, and synthetic opioids, results indicated that overall opioid fatality rates increased dramatically after the implementation of HB1. The results of this study provide increased knowledge for policymakers, which may ultimately lead to a decrease in opioid overdose fatality rates.

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Chapter 1: Introduction to the Study

Introduction

The United States is in the midst of an opioid epidemic (United States Department of Health and Human Services [H.H.S.], n.d.a). Jefferson County, Kentucky is among Kentucky counties that have been hardest hit by the epidemic. The Kentucky Office of the State Medical Examiner (n.d.) reported that the most common category of deaths statewide in 2016 was drug related deaths. Drug related deaths accounted for 35% of all deaths. Drug related deaths were followed by gunshot wounds at 18.9%, nearly half the number of deaths caused by drugs. Of those drug-related deaths, opioids were, by far, the largest class of drugs detected. Opioids accounted for 44.56% of drug-related deaths followed by benzodiazepines at only 16.44% of drug related deaths statewide in 2016 (Office of the State Medical Examiner, n.d.).

The Kentucky General Assembly passed House Bill 1 (HB1) in 2012 to reduce the number of prescription drug related deaths. HB1 defined a Prescription Drug Monitoring Program (PDMP) as having the purpose of monitoring prescribing habits and sharing prescription information among health care providers. One expected consequence of implementing the PDMP was to decrease the amount of prescription drugs available for diversion to the illicit market and, therefore, decrease the number of prescription drug related deaths in Kentucky. Little is known about how the implementation of Kentucky's PDMP might have affected overdose deaths related to non-prescription opioids, specifically heroin and synthetic opioids (Kentucky General Assembly, 2012).

This research examines the possibility that recent documented increases in heroin and synthetic opioid fatality rates are related to the implementation of Kentucky's PDMP. The target populations for this study was people who were arrested for opioid-related violations and people who died from opioid-related overdose in Jefferson County, Kentucky between the years of 2007 and 2017. The findings in this study provide valuable information to policymakers who are tasked with implementing programs to address drug related problems. The findings in this study provide policymakers with valuable information for consideration to spark positive social change. Ultimately, the implications for positive social change are measured in a decrease in opioid overdose fatality rates and lives saved.

The purpose of this research was to examine the relationship between the implementation of Kentucky's PDMP and the recent increase in heroin and synthetic opioid related fatality rates using a rational choice theoretical approach. Current research indicates that cost, availability and purity of available heroin are the primary drivers of a decision to switch from prescription opioid abuse to heroin use (Mars, Bourgois, Karandinos, Montero, & Ciccarone, 2014; Unick, Rosenblum, Mars, & Ciccarone, 2014).

Although price and availability have been found to be the primary considerations in making the choice to switch to heroin and synthetic opioid use, withdrawal symptom avoidance sometimes becomes the primary reason for the choice once a prescription drug abuser has already become addicted to opioids (Mars et al., 2014). Using these assumptions, the current study conducts various time series regression analyses assigning the year 2012, when Kentucky implemented a PDMP, as the primary choice point in time

and independent variable. In this study, dependent variables measuring overdose fatality rates were used with the identification of various drugs present at the time of death to quantify any significant relationships.

Problem Statement

Kentucky is ranked among the top 10 states in the nation for opioid-related overdose fatality rates (NIDA, 2018). Until recent years, the drug overdose problem in Kentucky was primarily the result of the misuse of various prescription drugs (Office of the State Medical Examiner, n.d.). Jefferson County, Kentucky has a problem with opioid overdose fatalities (Jefferson County Coroner's Office, 2018). Prescription opioids have been a major contributor to opioid overdose fatality statistics in Jefferson County, Kentucky (Office of the State Medical Examiner, n.d.).

The prescription opioid problem has not, however, been unique to Jefferson County, Kentucky. According to the Centers for Disease Control and Prevention (CDC, 2017), PDMPs have been created to address the prescription drug problem nationwide. The CDC (2017, para. 3) stated that PDMPs are "among the most promising state-level interventions" for addressing the prescription drug abuse problem.

In response to Kentucky's prescription drug overdose problem, the Kentucky General Assembly passed Kentucky's PDMP, as defined in HB1 in 2012 (Kentucky General Assembly, 2012). The intent of Kentucky's PDMP was to reduce prescription drug misuse by monitoring prescribing and dispensing practices and sharing information among prescription drug providers (Kentucky General Assembly, 2012).

Prescription opioids are among the prescription drugs that are monitored by PDMPs. Opioids are drugs that are either made from the opium poppy plant or created synthetically in legitimate or clandestine labs (National Institute on Drug Abuse [NIDA], n.d.). A primary medical purpose for opioids is pain management (NIDA, n.d.). Prescription opioids have historically played a significant role in the overall prescription drug overdose problem in Kentucky (Office of the State Medical Examiner, n.d.). Prescription opioids present a unique problem for addressing prescription drug misuse because opioids are not only legitimate and highly effective pain management medications but they are also addictive and desirable for drug dealers and misusers (NIDA, n.d.; Volkow, 2014).

Misuse of prescription opioids can ultimately lead to overdose incidents and death (Office of the State Medical Examiner, n.d.; Volkow, 2014). Prescription opioids can be found in the illicit market because they are diverted from licit to illicit use (White, Ready, & Katz, 2016). For the purpose of this study, prescription opioid diversion will be narrowly defined as when someone misuses prescription opioids that were prescribed for someone else.

Despite the implementation of Kentucky's PDMP, overall drug overdose fatality rates in Kentucky have continued to climb (Office of the State Medical Examiner, n.d.). Heroin and synthetic opioid use, primarily fentanyl, appear to be at least partially to blame for the increase in drug overdose fatality statistics in Jefferson County, Kentucky (Office of the State Medical Examiner, n.d.). The presence of opioids like heroin and fentanyl further complicates efforts to decrease drug overdose fatalities. Heroin is an

illicit opioid that is made from morphine, the natural substance found in the poppy plant (NIDA, n.d.). Heroin is used as a recreational drug for its intoxicating effects (NIDA, n.d.).

Fentanyl is a synthetic opioid that has medical purposes but is also created in illicit drug labs for illicit use (NIDA, n.d.). Heroin and Fentanyl that are created in clandestine labs cannot be regulated by PDMPs. An alarming finding for Kentuckians is that fentanyl, alone or in combination with heroin, was identified in 47% of all drug overdose fatalities in Kentucky in 2016 (Tilley & Ingram, n.d.).

Morphine was the most detected drug in overdose fatalities by the medical examiner in 2016. The detection of morphine can indicate either a morphine overdose or a heroin overdose. Heroin presents as morphine after it is metabolized by the body. This complicates the true measure of heroin's effect on the overall opioid overdose fatality rate because it makes it more difficult to pinpoint the exact drug that caused an overdose death (Tilley & Ingram, n.d.).

Polydrug use also complicates the exact identification of the lethal drug in an overdose death. Polydrug use is common in overdose deaths in Jefferson County, Kentucky (Jefferson County Coroner's Office, 2018). The Kentucky Medical Examiner's Office (n.d.) reports all drugs identified in the individual's body at the time of death on the toxicology report.

Kentucky's HB1 does not attempt to address heroin use or illicitly produced fentanyl use, only prescription drug misuse. An intended consequence of PDMP implementation is that the availability of prescription opioids for diversion to the illicit

market should decrease (White et al., 2016). The resulting lack of prescription opioid availability for misuse might encourage opioid misusers to make a choice to switch from prescription opioid abuse to heroin and illicitly produced fentanyl use.

In 2016, during the first Opioid and Heroin Awareness Week, former United States Attorney General, Loretta Lynch, addressed the opioid epidemic with students at Madison Central High School in Richmond, Kentucky. Lynch repeatedly claimed during her visit that heroin addiction is usually preceded by a prescription drug problem. Specifically, Lynch stated that, "sometimes doctors and family members will recognize someone's got a problem with pills and they'll remove them, they'll cut them off, and that is often when people will switch to heroin for the same effect" (WLKY News Louisville, 2016, 21:18).

Muhuri, Gfroerer, and Davis (2013) provided evidence to support the possibility of a drug policy creating unintended consequences when they found that there was a strong relationship between first time heroin users and those who have misused prescription painkillers. Alpert, Powell, and Pacula (2017) provide another example of drug policy and unintended consequences in their study concerning the relationship between the reformulation of OxyContin, a prescription opioid, and heroin abuse. OxyContin abusers made the choice to switch to heroin and fentanyl when their opioid of choice, OxyContin, was reformulated making it more difficult to crush the drug for inhalation or injection, the preferred method of use for OxyContin abusers (Alpert et al., 2017).

Purpose

The purpose of this quantitative research was to explore the possible relationship between the implementation of Kentucky's PDMP and the subsequent rise in heroin and synthetic opioid overdose deaths as an unintended consequence of the implementation of the PDMP. The null hypothesis for this study was that there is no relationship between the implementation of Kentucky's HB1 and the documented increase in heroin and synthetic opioid overdose rates in Jefferson County, Kentucky. The alternative hypothesis was that there is a relationship between the passage of Kentucky's HB1 and the documented increase in heroin and synthetic opioid overdose rates in Jefferson County, Kentucky. Through this study, I examined variables related to the supply and demand of prescription opioids and heroin and synthetic opioids and compared these variables along with the prescription opioid, heroin, and synthetic opioid overdose rates between the years of 2007 and 2017. Current literature shows that PDMPs can be successful for changing physician prescribing habits and for reducing prescription drug overdose incidents (Finklea, Bagalman, & Sacco, 2014). Little is known, however, about the possible unintended consequences of implementing PDMPs.

Alpert et al. (2017) researched the effects of the reformulation of OxyContin on the use of heroin. The researchers found that the reformulation created the unintended consequence of driving OxyContin misusers to switch to heroin use (Alpert et al., 2017).

In this study, I explored the possible relationship between Kentucky's PDMP and heroin and fentanyl overdose fatality rates to determine if Kentucky's PDMP has had the

unintended consequence of driving prescription opioid misusers to switch to heroin and fentanyl use.

A quantitative approach helped to identify and quantify possible relationships between the implementation of Kentucky's PDMP and the increase in heroin and fentanyl overdose fatality rates in Jefferson County, Kentucky. Time series analyses were conducted using the implementation of Kentucky's PDMP in 2012 as the independent variable. Prescription drug overdose fatality rates, heroin and synthetic opioid overdose fatality rates, and opioid prescribing rates over the identified time period were used as dependent variables to explore possible relationships from within a rational choice theoretical framework.

Significance

This study fills a gap in the literature concerning the nature of heroin and synthetic opioid use in the presence of Kentucky's PDMP, a policy that was intended to address prescription drug misuse. This study has the potential to reveal a deadly unintended consequence of a well-intentioned prescription drug regulation policy. This study is unique because there is very little current research that attempts to identify and quantify unintended consequences of PDMPs. Current research related to this study concerns the effectiveness of PDMPs and the choice variables related to making the switch from prescription opioids to heroin. There is an abundant amount of literature explaining these topics as well as the history of prescription opioid and heroin use. There are, however, very few studies that address the unintended consequences of initiating a PDMP.

The current state of heroin and fentanyl overdose fatalities in Jefferson County, Kentucky calls for a better understanding of what sparked and has driven the epidemic. The knowledge gained from this study could prove to be valuable for future policymakers concerned with authoring drug-related policy. The possibility of gaining knowledge in the area of unintended consequences of drug policy suggests serious positive social change implications. This knowledge could influence future drug policy considerations and ultimately save lives.

Rational Choice Theory

Rational choice theory was used as the theoretical framework for the current study. Rational choice theory posits that humans are rational beings (Beccaria, 1764; Cornish & Clarke, 1986). Because humans are rational beings, we make rational choices after weighing the perceived benefits against the perceived consequences of our choices.

The beginnings of rational choice theory can be found in the writing of Cesare Beccaria (Wright, n.d.). Beccaria wrote concerning the condition of 18th century law and punishment. According Beccaria (1764), the natural state of man is self-serving and individualistic. The creation of society caused a need for individuals to give up a degree of freedom and conform to the will of the society. The surrender of some freedoms is necessary to gain the benefits of living in a civilized and non-chaotic society. This social contract creates an environment in which people must weigh the benefits, the natural desires of individuals, against the consequences, or deterrent factors, of acting contrary to the laws of society (Beccaria, 1764). Beccaria (1764) further believed that for laws to be truly deterrent, punishments for violation of the laws should be swift and certain.

Swiftness and certainty of punishment establishes a stronger psychological link between the illegal action and the punishment. The psychological link enhances the desired deterrent effects of punishment (Beccaria, 1764).

Various academic works have included and expanded Beccaria's ideas. For example, Jeremy Bentham, who was also concerned with controlling human behavior by using effective laws and punishment. Bentham also opined that humans are motivated by the receipt of pleasure and the avoidance of pain (Wright, n.d.). For the purpose of this study, the pleasure and pain discussed by Bentham are equivalent to the benefits and consequences of criminal behavior, as discussed by Cornish and Clarke (1986).

From within the framework of rational choice theory, those who perceive that the benefits of committing a crime outweigh the perceived consequences for committing the same crime will make the rational choice to commit the act. The opposite is true when the consequences of committing the crime are perceived to outweigh the benefits of committing the same crime. When the perceived consequences outweigh the perceived benefits, crime is avoided (Beccaria, 1764; Cornish & Clarke, 1986).

This study was informed by rational choice theory to examine the possibility that Kentucky's PDMP played a part in the dramatic documented increase in the heroin and fentanyl overdose fatality rates in Jefferson County, Kentucky. If Kentuckians made a rational choice to switch from prescription opioid abuse to heroin and synthetic opioids, this choice would also be consistent with Skinner's (1938) operant conditioning theory.

Skinner (1938) explained that behavior can be encouraged through reinforcement or discouraged through punishment. The decision to switch from prescription opioid

abuse to heroin and fentanyl use is consistent with both positive and negative reinforcement The decision to switch to heroin and fentanyl abuse not only constitutes positive reinforcement due to the desired intoxicating rewards of continuing opioid abuse, but also negative reinforcement because the decision actively avoids the negative stimulus of enduring opioid withdrawal symptoms. From within a rational choice framework, both of the reinforcement stimuli mentioned would be considered benefits of choosing to switch to heroin and fentanyl abuse.

Research Questions

1. Did the implementation of Kentucky's HB1 change the rate of heroin and fentanyl overdose fatalities in Jefferson County, Kentucky?
    a. Have opioid prescribing rates decreased after the implementation of Kentucky's HB1?
    b. Have arrest rates for possession of heroin and synthetic opioids increased after the implementation of Kentucky's HB1?
    c. Have arrest rates for trafficking of heroin and synthetic opioids increased after the implementation of Kentucky's HB1?
    d. Is there a statistically significant difference in the opioid prescribing rate after the implementation of HB1?
    e. Is there a statistically significant difference in the prescription opioid overdose fatality rate after the implementation of HB1?
    f. Is there a statistically significant difference in the heroin and synthetic opioid overdose fatality rate after the implementation of HB1?

g. Is there a statistically significant relationship between prescribing rates and heroin and synthetic opioid overdose fatality rates?

Nature of the Study

The nature of this study was quantitative. Quantitative research is consistent with understanding relationships between variables. The variables in this research were those that coincide with the assumptions of rational choice theory. When faced with a choice of action, rational beings will weigh the benefits against the consequences of their actions (Cornish & Clarke, 1986). The intoxicating effects are desirable to opioid abusers and that withdrawal symptoms can be severe (U.S. National Library of Medicine, n.d.; Volkow, 2014).

After the implementation of Kentucky's PDMP, prescription drug abusers were possibly faced with the choice to discontinue opioid abuse and suffer opioid withdrawal symptoms, enter into drug rehabilitation treatment, or change to heroin and fentanyl use to continue receiving the intoxicating effects of opioids while simultaneously avoiding severe withdrawal symptoms. A rational choice in this position might be to change from prescription opioid abuse to heroin and fentanyl use.

Prescribing rates and overdose fatality rates for prescription drugs and heroin and fentanyl prior to the passage of HB1 provided a baseline for this study. The implementation of Kentucky's PDMP, in 2012, was used as the point in time when prescription opioid misusers might have been encouraged to make the switch to heroin and fentanyl abuse.

Changes in the drugs that have been identified in overdose toxicology reports after the passage of Kentucky's PDMP indicate a need for identifying and quantifying the possible interactions and relationships over time between the implementation of Kentucky's PDMP and prescription opioid, heroin, and fentanyl overdose fatality rates.

There are limitations when using public arrest records. First, one must consider the possibility of human error. The truthfulness of the data output relies on many officers inputting arrest data correctly. This accuracy limitation leads to another limitation when using public arrest data. There are various types of opioids, and other drugs, for which a person might be arrested. The Louisville Metro Police Department arrest record database includes arrests for both possession and trafficking in a controlled substance with no drug identified. Although these entries are sure to include opioid-related violations, the data cannot be used in this study due to the lack of opioid identification.

Changes in prescribing rates in Jefferson County, Kentucky also help to explain possible changes in the availability of prescription opioids for diversion in Louisville, Kentucky. A time series examination of the opioid prescribing rates and overall opioid overdose fatality rates in Louisville, Kentucky was conducted to evaluate the possible existence and strengths of relationships between the passage of HB1, the availability of prescription opioids for diversion, changes in overall drug overdose fatality rates, and increases in heroin and fentanyl overdose deaths.

Possible Types and Sources of Data

1. Opioid prescribing rates obtained from the CDC's (2018) U.S. Prescribing Rate Maps.
2. Annual opioid overdose fatality reports from the CDC Wonder database.
3. Arrest data obtained from the Louisville Metro Police Department's online arrest database.

Importance of This Study

The importance of this study is found in the positive social change implications. Understanding the possible negative consequences of drug policy implementation may help future policymakers to consider these consequences prior to policy implementation. The prediction of negative unintended consequences could lead to additional funding, for example, for the inclusion of drug treatment and public education initiatives and ultimately save many lives.

Summary

Jefferson County, Kentucky has a problem with opioid overdose fatalities. In 2012, Kentucky passed HB1 to address the prescription opioid overdose problem. HB1, however, did not address opioids such as heroin and synthetic opioids like fentanyl and other illicitly manufactured opioids. After the passage of HB1, the occurrence of heroin and synthetic opioid overdose fatalities increased dramatically.

This study was conducted to identify and quantify possible relationships between the passage of HB1 and the documented increase in heroin and synthetic opioid fatality rates. Supply and demand variables such as opioid-related arrest and prescription rates

were compared to the opioid-related overdose fatality rates during the time period between 2007 and 2017. The comparison of these variables helps to explain whether the implementation of HB1 helped to create an environment conducive to addicts switching from prescription opioid abuse to heroin and synthetic opioid use.

Furthermore, this research helps to fill the literature gap concerning negative unintended consequences of PDMP implementation. This research is timely and needed because the opioid epidemic is widespread and states across the nation are struggling to create policies that will effectively address the epidemic. There is currently very little research concerning the unintended negative consequences of PDMP implementation.

To provide a better understanding of the history and current state of opioid use and abuse, I discuss in Chapter 2 the current literature pertaining to opioids in the United States, prescription opioid diversion, PDMP, unintended consequences of PDMP implementation, the gateway question, and motivation for switching from prescription opioid abuse to heroin use. Additionally, I address the social, economic, and political implications of the opioid crisis.

Chapter 2: Literature Review

Introduction

The Walden University Library was used to perform the majority of the literature review research for this study. Databases such as Ebsco and Proquest were accessed through the Criminal Justice Database on the Walden University Library website. Google scholar was also used to locate current literature. Most of the literature was located by researching references listed in the articles found in the databases. Information from various government websites is also cited.

Key search terms used were *opioid, heroin*, and *PDMP related*. Combinations of the key search terms and words such as *history, unintended consequences, gateway*, and others were also used. As mentioned, most of the literature research was done by locating and searching the references listed in articles found using the key search terms.

Most of the literature referenced in Chapter 2 was published within the current and past seven years, from 2012 through 2019. Some seminal or more aged literature was used to clarify topics such as the long-time utilized rational choice theory. Information from the resources is presented in Chapter 2.

Jefferson County, Kentucky's drug overdose fatality problem has undergone dramatic changes in recent years. The early driver of drug overdose deaths was prescription drug misuse. Now, the synthetic opioid fentanyl, alone or in conjunction with heroin, has overtaken prescription drugs as the most detected drugs identified in toxicology reports for overdose fatality victims (Office of the State Medical Examiner,

n.d.). The sudden and dramatic change followed the implementation of Kentucky's PDMP in 2012.

The intent of Kentucky's PDMP was to decrease the rate of prescription drug misuse and overdose incidents. A successful PDMP would have the intended positive consequence of allowing fewer prescription drugs to be available for diversion to the illicit market (Kentucky General Assembly, 2012).

Prescription opioids have been top contributors to the prescription drug overdose fatality problem prior to and after the implementation of Kentucky's PDMP (Office of the State Medical Examiner, n.d.). Decreasing the availability of prescription opioids through PDMP regulation would have left the prescription opioid addict with a choice to make. Options could have included cessation of opioid abuse and suffering opioid withdrawal symptoms, entering drug rehabilitation treatment, or switching to an available substitute for the addict's drug of choice.

For the prescription opioid addict, any of the choices could be considered rational. In this research, I examined the possible existence and strengths of relationships between the implementation of Kentucky's PDMP and prescription opioid, heroin, and synthetic opioid overdose rates before and after the implementation of Kentucky's PDMP using a rational choice framework. I explored the possible relationships to obtain a better understanding of the changes that have been documented concerning prescription opioid overdose fatality rates and the possible substitution choice of heroin and synthetic opioid use and, ultimately, the dramatic documented rise in heroin and synthetic opioid overdose fatality rates.

PDMPs are designed to decrease the availability of prescription drugs for diversion and misuse (Kentucky General Assembly, 2012). Availability, or the lack thereof, is one of the primary reasons that prescription opioid users make the switch to heroin (Alpert et al.,2017; Beletsky, 2018; Fink et al., 2018; Li et al., 2014; Nam, Shea, Shi, & Moran, 2017). Prescription opioid addicts make the switch to heroin to avoid withdrawal symptoms when prescription opioids are not available (Alpert et al., 2017; Cicero, Ellis, Surratt, & Kurtz, 2014; Mars et al., 2014).

It is logical to suppose that Kentucky's PDMP implementation had the consequence of forcing prescription opioid addicts to weigh their options and make a choice about which path to follow in the absence of available prescription opioids. It is also logical to suppose that many prescription opioid addicts would choose to make the switch to heroin and synthetic opioids to avoid withdrawal symptoms and continue receiving the desired intoxicating effects of opioid misuse. Finally, following this reasoning, I explored the possibility that the implementation of Kentucky's PDMP had the chilling unintended consequence of driving prescription opioid addicts to heroin and synthetic opioid use thereby dramatically increasing the heroin, synthetic opioid, and overall opioid fatality rates.

In the following sections, I discuss the current literature concerning several related topics. First, I discuss a brief history of opioids and the timeline of events that created the current opioid epidemic. I then discuss the diversion of prescription drugs as a driver of the opioid problem that led to the development of PDMP across the nation and specifically in Kentucky. I examine the gateway question and withdrawal avoidance as

they are related to the implementation of Kentucky's PDMP and the choice to switch from prescription opioid misuse to heroin and synthetic opioid use. I also discuss the social, economic, and political implications of the opioid overdose epidemic. Finally, I describe rational choice theory and how it might help to analyze the recent shift from prescription opioid abuse to heroin and fentanyl use.

Framework

Rational choice theory explains criminal behavior by considering the justification used in a decision whether or not to commit a crime. Rational choice theory assumes that humans are rational beings and that we make the most rational behavioral choices after weighing the benefits against the consequences of a specific behavior. If the benefits of an action outweigh the consequences, the rational choice would be to proceed with that action. If the consequences outweigh the benefits a specific behavior, the rational choice would be to refrain from the behavior (Beccaria, 1764; Cornish & Clarke, 1986).

Rational choice theory has been applied in studies of drug use. In fact, Cornish and Clarke (1986) used a study of opioid misuse to help explain the theory. The study used in Cornish and Clarke's (1986) book, "The Reasoning Criminal: Rational Choice Perspectives on Offending," concerned initiation into opioid misuse. It is clearly established by the authors of rational choice theory that the theory is an appropriate theoretical framework for studying the rationale for drug initiation, continuance, and cessation.

Although the choice to switch from prescription opioids to heroin and illicitly manufactured synthetic opioids is not a choice of whether to commit a crime but rather a

choice between two similar crimes, rational choice theory is an appropriate theoretical framework for this study. For the choice in question, rational actors would still weight the benefits against the consequences of changing behavior and decide.

From within the rational choice theoretical framework, benefits of switching from prescription opioid use to heroin and fentanyl might be the avoidance of withdrawal symptoms, continuing to achieve the state of intoxication gained through prescription opioid abuse, or even avoiding the social stigma associated with participation in a drug rehabilitation program. These benefits might be weighed against negative consequences like, arrest, overdose, and death. While it seems unlikely that a rational person would choose to initiate heroin and synthetic opioid use with such extreme negative consequences, it is only necessary for the addict to weigh the near certain benefits against his or her perception of the probability of the negative consequences occurring. If the addict does not consider the probability of arrest, overdose, or death to be high enough, he might consider it a rational choice to proceed with the dangerous activity of heroin and fentanyl use.

A Brief History of Opioids

Opioids are a broad assortment of drugs that are derived from, or mimic the effects of, the chemicals naturally found in the opium poppy plant (NIDA, 2018). Opioids are primarily used in the medical field to manage pain, but they are also used for other issues like coughing and diarrhea (NIDA, 2018).

In addition to the medical qualities of opioids, they can produce an intoxicated feeling that can encourage misuse (NIDA, 2018.). People who misuse opioids can obtain

them through various sources. Prescription opioids can be obtained for misuse through the diversion of legally prescribed medications to the illicit market. Heroin and synthetic opioids can be illicitly manufactured in clandestine labs and obtained through personal-level drug transactions. In fact, the overwhelming majority of fentanyl overdose deaths are attributed to fentanyl made illicitly rather than regulated but diverted prescription fentanyl (Drug Enforcement Administration [DEA], 2017).

Due to the diverse variety of drugs that are included under the broad canopy of opioids, they appear in all five schedules of the DEA's schedule of controlled substances. Prescription opioids are listed in DEA schedules II through V depending upon their acceptance for legitimate medical use and propensity for addiction (DEA, n.d.).

Fentanyl is a synthetic opioid that has an accepted medical use, but it can also be manufactured in unregulated clandestine laboratories and sold in the illicit market to effectively circumvent regulation (DEA, 2017, n.d.). Regulated fentanyl, used for legitimate medical purposes, is a schedule II-controlled substance due to its accepted medical purpose and high propensity for addiction (DEA, n.d.). Fentanyl is more potent than other prescription opioids, heroin, morphine and other synthetic opioids (DEA, 2017; Rothberg & Stith, 2018).

Heroin, a drug for which there is no accepted medical application, is a Schedule I controlled substance (DEA, n.d.). Both medical use and non-medical misuse of opioids can cause dependence and addiction (NIDA, n.d.). Addiction and misuse of opioids can cause unintentional overdose fatalities (NIDA, n.d.). A discussion of the current state of

the opioid epidemic should begin with a clear understanding of the history of opioids and opioid addiction in the United States.

Opioid Use in the United States

The general use of opium predates the independence of the United States by millennia. Research has identified the mention of opium and its intoxicating effects in ancient writings as far back as 1550 B.C. (Wright, 2011). Opioids have made their way into the United States through various routes.

Opium and its derivatives have had a pronounced impact on the practice of medicine throughout American history. From the use of laudanum as a physician's staple medication in the 1800s to the current state of opioid overdose fatalities of epidemic proportion, opioids have occupied a considerable portion of American medical and addiction history (Aronson, 2011; Tricky, 2018).

Laudanum was created by Paracelsus in the late 1400s to mid-1500s by mixing opium and alcohol (Aronson, 2011). Laudanum was a staple medication used by American physicians in the late 1800s (Aronson, 2011). The mixture was used for various ailments ranging from sleeping aids for restless infants to pain management (Aronson, 2011; Trickey, 2018).

A widely accepted explanation for 19th century opioid addiction began with a combination of the isolation of morphine from opium in 1804 and the perfection of the hypodermic syringe in the mid-1860s (Aronson, 2011: Trickey, 2018). In 1804, a German scientist named Friedrich Serturner isolated morphine from opium and created a water soluble, and therefore injectable, form of rapid-acting pain relief (Aronson 2011). More

importantly, however, for discussions involving historical drug policy is morphine's use for various female medical issues (Trickey, 2018). Popular use of morphine in the late 1800s for problems like menstrual cramps and nervous diseases made middle to upper-class White women the leading demographic for opioid addiction where they represented 60% of opioid addicts (Trickey, 2018).

The United States Civil War during the early to mid-1860s has also been credited with 19th century morphine addiction (Lewy, 2013; Trickey, 2018). Lewy (2013), explains that the hypodermic syringe gained popularity throughout the Civil War. Civil War field physicians more commonly used powdered morphine applied directly to open wounds while physicians practicing away from the battlefield freely administered opium for pain relief (Lewy, 2013). The two observations by Lewy (2013) contradict the popular belief that the syringe played an important role in Civil War era opioid addiction. In fact, Guevremont, Barnes, and Haupt (2018) and Lewy (2013) argued that what we call addiction today, was referred to as a simple moral weakness, or bad habit, in the Civil War era and shortly thereafter. Therefore, Lewy (2013) rejected the popular idea that the phrase "army disease," documented during and after the Civil War, referred to morphine addiction caused by exposure to morphine during the Civil War.

There were no laws in the United States to regulate opioids prior to 1909, when the Pure Food and Drug Act required only that narcotic contents be listed on patent medicines (Aronson, 2011). Only two years later, the first International Opium Commission concluded that opium was a known "evil" but failed to enact legislation to regulate its use (Aronson, 2011).

The lack of opium regulation changed in the early 1900s with the arrival of Chinese immigrants. Chinese immigrants brought the practice of opium smoking and the social tradition of smoking opium in an opium den with them to the United States (Trickey, 2018). Opium dens in the United States were frequented by Chinese workers and lower-class White males (Trickey, 2018). Trickey (2018) argues that it is this change in demographics that led to subsequent regulation of opium in the United States. According to Trickey (2018) it was much easier politically to push legislation against Chinese and lower-class White male opium addicts than it was previously, when the primary opioid addict demographics included mainly upper-class White women and men returning home from the Civil War. In 1909, a bill was passed that made the importation of opium prepared for smoking a crime with a penalty of up to two years in prison (Trickey, 2018).

The Harrison Act of 1914 was the first legislation to restrict the use of opium, and other narcotics, to medical use only (Aronson, 2011). Much later, during the Reagan era War on Drugs, harsh sentencing for drug offenders accompanied what appeared to be a return to class and race-related politics (Trickey, 2018). Trickey (2018) discovered that today's opioid addicts are primarily White males and elderly people suffering from chronic pain from across the spectrum of social class. The tendency to identify the current opioid epidemic as a medical problem rather than a criminal problem is reminiscent of earlier days in America when opium use became a criminal issue only after Chinese immigrants and lower-class individuals became addicted (Trickey, 2018).

Considering the negative historical experiences with opioids and early legislation to regulate opium and opioids, it is difficult to imagine that modern physicians could be misled regarding the negative consequences of opioid use. However, HHS (n.d.a) explained that in the late 1990s, pharmaceutical companies misled physicians to believe that opioid pain relievers were not addictive. A simple historical review could have directed physicians to see beyond the misleading sales pitches of pharmaceutical companies and predict the oncoming wave of prescription opioid addicts. However, misguidance by the pharmaceutical companies led to a large increase in prescription rates for opioids across the United States (HHS, n.d.a).

Many new generation prescription opioid addicts began with a steady supply of prescription medication. The primary method identified for obtaining prescription opioids was the diversion of prescription opioids from friends, family, and drug dealers in the illicit market (White et al., 2016). Poor prescribing habits and the diversion of opioids to the illicit market have helped to fuel a national prescription opioid crisis that has proven deadly for numerous Americans (HHS, n.d.a).

Prescription Opioid Diversion

The diversion of prescription opioids was a major driver of the opioid overdose fatality crisis (HHS, n.d.b; McCabe, West, & Boyd, 2013; Pit et al., 2018). For the purpose of this study, opioid diversion occurs when prescription opioids are misused either by someone other than the legally prescribed user or by someone who has a legal prescription but uses the opioids in a manner inconsistent with the prescription. Inconsistent uses include actions such as taking a higher than prescribed dosage and

taking leftover prescription opioids for purposes other than the reason for which the opioids were prescribed. Researchers have indicated various methods for obtaining diverted prescription drugs (Gau & Brooke, 2017; White et al., 2016).

Studies have shown that the primary sources for obtaining diverted prescription opioids are family members and friends (Gau & Brooke, 2017; White et al., 2016). Doctors and other health care providers are also recognized sources for obtaining prescription drugs (McCabe et al., 2013; White et al., 2016). Improper prescribing practices by doctors and other health care providers has contributed to the availability of prescription opioids that could be diverted to illicit use (Dubois et al. 2016; HHS, n.d.b). A recent review of the existing literature confirmed that emergency departments were significant contributors to the diversion and misuse of prescription opioids (Lyapustina et al., 2017). A recent study of high school seniors revealed that of the 13% of high school seniors reporting prescription opioid misuse, the majority, 45%, obtained them from an emergency room physician (McCabe et al., 2013). Other physicians and dentists also contributed to the obtainment and misuse of prescription opioids by 38.3% and 27.1% respectively (McCabe et al, 2013).

Pharmaceutical companies misled physicians in the late 1990s to believe that opioid pain relievers were not addictive (HHS, n.d.b). This information alone makes it appear that pharmaceutical companies were the main culprits in the prescription opioid crisis. However, Dubois et al. (2016) identified various recurring individual characteristics among physicians who had been investigated for improper prescribing practices. Furthermore, HHS (n.d.b) reported that the majority of opioid prescriptions

have been written by a small number of doctors. Doctor shopping, visiting multiple doctors to obtain multiple prescriptions, is another method of acquisition used by prescription opioid misusers (White et al., 2016; Van Hout, 2014).

Harocopos and Bennett (2015) identified three distinct initiation routes into the misuse of opioids. All three initiation routes rely on the diversion of prescription opioids in order to sustain a prescription opioid addiction. First, heroin was a popular drug among specific subcultures throughout the 1960s and 1970s. Today's older opioid misusers tended to have been holdovers from the that era (Harocopos & Bennett, 2015). This first group began opioid use with heroin but, in the modern era, they shifted to misusing prescription opioids that were diverted to the illicit market (Harocopos & Bennett, 2015). Recent initiates were more likely to have begun prescription opioid misuse from the other two routes, recreational or medical initiation (Harocopos & Bennett, 2015). Regardless of the initiation route, diversion has clearly played an important role in the current epidemic of prescription opioid misuse and overdose fatalities (White et al. 2016).

PDMP

Poor prescribing practices, diversion, and abuse of prescription drugs can lead to addiction, overdose, and, in many cases, death. Prescription drug overdose fatality rates in the last decade have exposed a need for tighter regulation of prescription drugs. Prescription drug overdose and fatality rates in the United States have led to the implementation of PDMPs across the nation. PDMP regulations are implemented at the state level and they vary by state.

PDMPs are implemented to address prescription drug misuse in general by monitoring prescribing and dispensing practices concerning controlled substances. Theoretically, PDMPs decrease the frequency of poor prescribing habits and the diversion of prescription drugs to the illicit market (Gau & Brooke, 2017; Kentucky General Assembly, 2012). PDMPs attempt to control diversion methods such as doctor shopping and prescription fraud by directing physicians and pharmacists to access individual patient records regarding the prescribing and dispensing of prescription drugs (Kentucky General Assembly, 2012).

Prescription opioid overdose fatality rates have been a primary concern in the implementation of PDMPs. The Kentucky General Assembly (2012) addressed Kentucky's prescription opioid overdose problem through the passage of Kentucky's HB1. HB1 targeted pain management facilities and provided funding for the upgrade and operation of the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system, Kentucky's prescription monitoring database and the heart of Kentucky's PDMP (Kentucky General Assembly, 2012).

The CDC (2017, para. 3) states that PDMPs are "among the most promising state-level interventions" for addressing the prescription drug abuse problem. Early literature on the topic confirms the CDC's (2017) statement to an extent. Early literature shows that PDMPs can be successful for changing physician prescribing habits and for reducing prescription drug overdose incidents (Finklea et al., 2014).

Current literature, however, suggests that PDMPS are not living up to the "promising" label given to PDMPs by the CDC (Compton, Jones, & Baldwin, 2016;

Hsien-Chang, Wang, Boyd, Simoni-Wastila, & Buu, 2018; Li, G. et al., 2014; Nam et al., 2017). Compton et al. (2016) claim only some success for states implementing thorough initiatives, including PDMPs, to decrease prescription opioid overdose fatalities. Hsien-Chang et al. (2018) studied prescribing habits and concluded that PDMPs have not been found to be effective for changing opioid prescribing habits for non-cancer chronic pain sufferers. Li et al. (2018) found that between the years of 1999 through 2008 overdose fatality rates increased and that fatality rates were actually higher in states with PDMPs compered to states without PDMPs. Nam et al. (2017) found no statistical evidence that the existence of a PDMP reduces opioid overdose fatality rates.

One recent study found the disabled and older Medicare recipients to be among the population achieving limited success in reducing opioid use (Moyo et al., 2017). Another study was inconclusive but provided evidence of unintended consequences of PDMP implementation, a primary consideration of the current study (Fink et al., 2018).

Unintended Consequences of PDMP

Two potential unintended consequences of PDMP that have been mentioned in current literature are the concern over limited access to legitimate prescription drugs for pain management and the movement of illicit prescription drug activities to neighboring states (Pit, Humphreys & Brandeau, 2018; Finklea et al., 2014; NIDA, n.d.). Muhuri et al. (2013) strengthened the argument that drug policy could create unintended consequences when they found that there was a strong relationship between first time heroin users and those who have misused prescription painkillers. This relationship adds another angle to the argument that prescription opioid misusers are willing to substitute heroin and

synthetic opioids for more expensive and less available prescription opioids. The switch from prescription opioids to heroin and synthetic opioids might be an unintended consequence of the implementation of a PDMP that successfully removes divertible prescription opioids from the illicit market (Compton et al., 2016; Pitt, Humphreys, & Brandeau, 2018). In fact, in many current studies, the authors elude to the possibility that PDMPs create the undesirable and unintended consequence of encouraging the move to cheaper heroin and fentanyl when prescription opioids are unavailable due to the implementation of a PDMP (Compton et al., 2016; Beletsky, 2018; Fink et al., 2018; Li et al., 2014; Nam et al., 2017; Pitt et al., 2018).

Alpert et al. (2017) provide another example of drug policy and unintended consequences in their study concerning the relationship between the reformulation of OxyContin, a prescription opioid, and heroin abuse. OxyContin abusers made the choice to switch to heroin and fentanyl when OxyContin was reformulated making it more difficult to crush for inhalation or injection, the preferred method of use for OxyContin abusers (Alpert et al., 2017). Recent initiates to heroin use in the qualitative Alpert et al. (2017) study complained that the earlier form of OxyContin had become increasingly difficult to find causing many to substitute heroin use for their prescription opioid of choice, OxyContin.

The Gateway Question: Does Prescription Opioid Addiction Lead to Heroin Use?

Current literature indicates that the modern generation of heroin users is more likely than not to have initiated opioid misuse through the non-medical use of prescription opioids (Cicero et al., 2014; Unick et al., 2014). Studies have also shown that

most heroin users would have preferred to continue using prescription opioids, most specifically OxyContin, over making the switch to heroin use (Cicero et al., 2014; Mars et al., 2014; Unick et al., 2014). However, heroin and fentanyl are cheaper and more readily available than prescription opioids (Cicero et al., 2014; Rothberg & Stith, 2018). When the cost of prescription opioids was too great or there was a lack of prescription opioid availability, prescription opioid abusers have accepted heroin as a substitute drug (Alpert et al., 2017; Rothberg & Stith, 2018).

Many current generation heroin misusers made the switch to heroin after having already become addicted to prescription opioids (Cicero et al., 2014; Mars et al., 2014). At least one study has added the level of purity and type of heroin available to the list of reasons why some people make the switch and others do not (Mars et al., 2014). The study was conducted in two cities. The cities were San Francisco, where low-purity black tar heroin was available but more expensive, and Philadelphia, where high-purity powder heroin was available at a lower cost (Mars et al., 2014). Although some San Francisco abusers made the switch, they were more likely to seek treatment rather than initiate heroin use (Mars et al., 2014). Those in Philadelphia with a high-purity, low cost heroin option, were more likely to make the switch from prescription opioid abuse to heroin use (Mars et al., 2014). Studies indicate that heroin cost, availability, and purity are all predictors for switching from prescription opioid abuse to heroin use (Alpert et al., 2017; Cicero et al., 2014; Mars et al., 2014).

Addiction to prescription opioids generates a need for users to avoid withdrawal symptoms. The switch from prescription opioid abuse to heroin use has been regularly

linked to the higher cost and lower availability of prescription opioids and the purity and availability of heroin (Alpert et al., 2017; Cicero et al., 2014).

Withdrawal Avoidance

The main purpose of the current study was to identify and quantify any possible relationships with the implementation of Kentucky's PDMP and a documented increase in heroin and synthetic opioid overdose fatalities. It is important, however, to note that Van Hout (2014) cited the use of codeine for withdrawal symptom avoidance. Codeine is considered a "weak" opioid but it is problematic because it is also addictive when misused and it can be purchased in low dosage without a prescription (Van Hout, 2014). The substitution of codeine for methadone or heroin for the management of withdrawals strengthens the idea that opioid addicts will misuse substitute opioids to avoid withdrawal symptoms (Alpert et al., 2017; Van Hout, 2014). The substitution of codeine for methadone or heroin is, admittedly, going in the opposite direction by substituting a weaker opioid for a stronger but unavailable prescription opioid. The focus of this study, in opposition, concerns the substitution of a stronger unregulated opioid, heroine or fentanyl, in the absence of prescription opioids.

After having become addicted to prescription opioids, many addicts have found it difficult to either afford or locate enough prescription opioids to avoid withdrawal symptoms (Cicero et al., 2014; Mars et al., 2014). When offered the lower-cost and more readily available heroin substitute, many have chosen to make the switch to heroin use (Cicero et al, 2014; Mars et al., 2014).

Fentanyl

Fentanyl is a synthetic opioid. Synthetic opioids are manufactured in a laboratory without the use of the opium poppy plant (DEA, n.d.). The medical uses of fentanyl are typically for the treatment of severe and post-surgical pain (NIDA, 2016). The DEA (n.d., para. 4) reports that fentanyl is "50-100 times more potent than morphine and 30-50 times more potent than heroin." Due to the high potency, fentanyl can be deadly at relatively low doses (DEA, n.d.).

In a 2008 study, Hall et al. reported that 50% of opioid overdose fatalities in West Virginia were the result of diverted prescription fentanyl. Prescription opioids are no longer the primary source for opioid overdose fatalities. Government agencies currently report that illicitly manufactured fentanyl is the primary source for the majority of fentanyl-related overdose fatalities (DEA, n.d.; NIDA, 2016).

Illicitly manufactured fentanyl is sold in various forms including powder, spiked blotters, combined with heroin, as a substitute for heroin, or in the form of tablets that mimic less potent opioids (NIDA, 2016). Regardless of whether the primary source for fentanyl is diverted prescription fentanyl or illicitly manufactured fentanyl, fentanyl has become the most commonly identified drug in toxicology reports in Kentucky (Office of the State Medical Examiner, n.d.).

Supply and Demand

PDMPs are meant to reduce the supply of prescription opioids available for misuse (CDC, 2017; Kentucky General Assembly, 2012). If a PDMP has been successful in reducing the illicit supply of prescription opioids, addicts were forced to make a

choice. One option for addicts is to substitute their opioid of choice for another form of opioid.

The interplay of supply and demand variables could encourage prescription opioid misusers to make the switch to heroin and fentanyl use. Fewer prescription opioids, driving the price of diverted prescription opioids up, mixed with a steady supply of heroin and illicitly produced fentanyl, driving the heroin and fentanyl prices down, interact with the continuing demand for opioids to make switching to heroin and fentanyl appear to be the rational choice for prescription opioid misusers.

Social Implications

Current literature discusses multiple social implications of the modern opioid overdose epidemic. Governments at the state and federal levels have attempted to address the opioid crisis through legislation. Government legislation has sparked a number of social concerns for researchers.

Class, Race, and Public Opinion

Public opinion has been somewhat fluid concerning drug use and abuse. Social class and race appear to have played important roles in defining and addressing drug use problems. Opioids, in particular, have a long history of class and race-related policy and legislation. There was no criminalization of opioid use until opium dens, frequented by Chinese immigrant workers and lower-class Whites, replaced civil war veterans, middle to upper-class White women, and elderly citizens suffering from chronic pain as the primary users of opium (Trickey, 2018).

Trickey (2018) briefly mentioned the tough on drugs policies and harsh sentencing for predominantly Black and Hispanic drug offenders during the Reagan-era War on Drugs. McLean (2017) and Trickey (2018) contrasted the criminalization of drug use for previous generations of addicts with the relaxed view of addiction as a medical problem for today's opioid addicts. Today's opioid addicts are primarily White males and elderly people suffering from chronic pain. McLean (2017) argued that it has been much easier to gain political support for anti-drug legislation when the primary group having been targeted was from minority and lower social statuses.

Pain Management

A common concern in current literature has been the question of whether patients receive the most adequate treatment for pain as determined by their physician (Guevremont et al., 2018, Pit et al., 2018). Guevremont et al. (2018) argued that physicians are better situated than politicians to make treatment decisions based on their relationships with each individual patient. The researchers also acknowledged, however, that opioid treatment has the possibility of reaching beyond the intended patient through diversion thereby creating a broader social problem for which the government might be better situated to address (Guevremont et al., 2018). The concern for Guevremont et al. (2018) is that the limitations on physician autonomy for treating the individual patient on a case-by-case basis results in one size fits all legislative treatment rather than treatment by physicians, who are already monitored by state medical boards and who are better situated to make individual treatment decisions.

Opioid Maintenance Treatment

The primary use for opioids in a medical setting is the management of pain. In addition to pain management, certain opioids such as methadone and buprenorphine are used in opioid maintenance treatment for people who are already addicted to opioids (Guevremont et al., 2018). There is concern that a series of regulations by the federal government curtails adequate access to maintenance treatment for opioid addicted patients (Guevremont et al., 2018). Beginning with the Harrison Narcotics Act of 1914 and continuing through the Controlled Substances Act of 1970 and the Drug Abuse Treatment Act of 2000, the United States government has placed limitations on opioid maintenance use as a treatment for opioid addiction (Guevremont et al., 2018).

Diversion Through Poor Storage and Disposal Practices

Another social concern that has been thoroughly studied is the diversion of prescription opioids to the illicit market (Dubois et al., 2016; Fujii, et al., 2018; Gau & Brooke, 2017; White et al., 2016). Current studies indicate that excessive prescriptions and improper storage and disposal of unused prescription opioids contribute to the diversion of prescription opioids (Fujii et al., 2018; McDonald, et al., 2017). Fujii et al. (2018) found that patients have historically been prescribed excessive amounts of opioids after certain surgeries and that the number of opioids prescribed after surgery varied by physician. When patients obtain more opioids than needed to complete recovery, it can result in having leftover opioids that can be easily diverted to illicit use (Fujii et al., 2018). Many patients with leftover prescription opioids fail to properly dispose of the excess medication (Fujii et al., 2018; McDonald et al., 2017). The failure to dispose of

excess opioids contributes to the addiction and overdose epidemic (McDonald et al., 2017). Fujii et al. (2018) and McDonald et al. (2017) suggest that educating patients on the need for proper use, storage, and disposal of opioids could lead to improved outcomes for fighting the diversion of opioids to the illicit market. The findings of the McDonald et al. (2017) study are particularly troubling because their findings related particularly to households with children present.

Involuntary Civil Commitment

Many states have enacted legislation that allows the involuntary civil commitment of addicts for treatment with very little, if any, due process (Bhalla, Cohen, Hupt, Stith, & Zhong, 2018). The legislation addresses opioid addiction as a medical condition rather than a criminal choice (Bhalla et al., 2018). Involuntary civil commitment is intended to separate the addict from illicit sources of opioids and some states provide addiction treatment while the addict is involuntarily committed (Bhalla et al., 2018). In essence, involuntary commitment is used to protect addicts from harming themselves by isolating them from society and providing treatment for their addiction (Bhalla et al., 2018). A major concern for Bhalla et al., (2018) is the lack of evidence that patients actually receive effective treatment while involuntarily committed. One reason that this is exceptionally concerning from a social standpoint is the implication that an addict's tolerance to opioids decreases while committed and, when released from involuntary commitment, the addict is at a higher risk for opioid overdose (Bhalla et al., 2018). This is one more example of unintended consequences of a well-meaning government legislation.

Implications for Addicts Seeking Justice

Fresher (2018) discusses the plight of addicts who seek damages in courtrooms across the United States but are denied justice due to the "wrongful conduct rule." The wrongful conduct rule refers to the notion by judges and juries that addicts are not entitled to damages because their addiction is, at least in part, due to their involvement in illegal activity (Fresher, 2018). Unfortunately, many opioid addicts have become addicted through no fault of their own without having made a single criminal choice (HHS, n.d.a). Poor prescribing habits fueled by false pharmaceutical company sales pitches concerning the addictive qualities of modern opioids has led to many patients having been improperly treated with opioids and having become addicted (HHS, n.d.a). In these instances, it hardly seems just for patients to be denied the opportunity to receive damages from those who contributed to their condition. The application of the wrongful conduct rule appears to be an unjust negative societal implication of the current state of opioid addiction.

Economic Implications

There is plenty of evidence in current literature to confidently state that the opioid crisis has resulted in an enormous economic burden in the United States. It is difficult to report an exact dollar amount of the financial burden created by the epidemic because various studies use different measures. Common measures have been large increases in medical care and treatment of opioid addicts (Hollingsworth, Ruhm, & Simon, 2017; Fudin, 2015; Litton, 2018) Other measures have included lost productivity, costs incurred

by insurance providers, costs incurred by Medicare and Medicaid, and foreign aid to curtail opioid production and trafficking.

Overall, it has been estimated that the opioid epidemic has cost the United States more than one trillion dollars between the years 2001 and 2017 (Litton, 2018). In 2007 alone, the costs were estimated at 55.7 billion dollars (Hollingsworthet al., 2017; Meyer, Patel, Rattana, Quock, & Mody, 2014). Litton (2018) referenced a report by the non-profit organization, Altarum, that estimated an additional 500-billion-dollar burden to come between the years between 2017 and 2020.

Litton (2018) reported that lost earnings and productivity due to overdose deaths are the largest contributors to the financial burden of the opioid epidemic. The cost of earnings and productivity loss were estimated at 800,000 dollars per opioid overdose victim (Litton, 2018). The estimate includes the loss of tax revenue as overdose victims are removed from the workforce (Litton, 2018).

Healthcare costs were estimated by Litton (2018) to be 215.7 billion dollars between 2001 and 2017. Medicaid has covered much of the healthcare financial burden (Litton, 2018). Hollingsworth, et al. (2017) reported that Medicaid covers an average of 5,874 to 15,183 dollars per year on opioid-related health care. Medicare was the primary payer for heroin overdose victims and Medicaid was the primary payer for prescription opioid overdose victims between 2001 and 2012 (Hsu, McCarthy & Stephens, 2017). During the time period between 2001 and 2012 prescription opioid overdose victims presented a larger financial burden, in part due to the fact that heroin overdose victims

were more likely to have left the healthcare facility against medical advice (Hsu et al., 2017).

Financial aid provided to the states by the federal government has also contributed to the financial burden as a result of the opioid overdose epidemic. In 2016, Congress passed the Century Cures Act and it was signed by President Obama to provide financial assistance to states for the purposes of primary and secondary prevention measures between 2016 and 2018 (Sarpatwari, Sinha & Kesselheim, 2017).

In addition to state funding, the federal government also provides financial assistance to foreign countries to help combat the trafficking of opioids and other illicit drugs into the United States (Felter, 2017). According to Felter (2017), The United States has provided almost three-billion-dollars to Mexico, and an additional near ten-billion-dollars to Colombia to combat the illicit drug trade that funnels opioids and other drugs into the United States.

Political Implications

The opioid overdose epidemic has certainly entered the realm of U.S. politics. Politicians and voters are using the issue to campaign and make political choices respectively (Gibson, 2018; Smith, 2018). Political candidates from both sides of the aisle are using the issue to gain political favor (Gibson, 2018). Both Republicans and Democrats seeking office have taken a stand in one way or another in the fight to reduce opioid abuse and overdose fatalities (Gibson, 2018). The primary difference between Republican and Democrat parties has been said to be the way in which each party sees the appropriate response to the epidemic (Gibson, 2018; McDonough, 2016; Smith,

2018). Republicans have sought a law enforcement approach while Democrats have sought a treatment-based approach (Gibson, 2018; McDonough, 2016; Smith, 2018).

Just prior to the 2018 midterm elections, President Trump claimed a bipartisan victory after signing legislation that would address the opioid epidemic with an additional six-billion dollars to increase both law enforcement efforts, historically promoted by the right, and access to medical treatment for opioid addiction, historically promoted by the left (Jackson & Fritze, 2018).

Research has suggested that there are underutilized alternatives to opioids for effective pain management (Atkinson, Schatman, & Fudin, 2014; Dennenberg & Curtiss, 2016; Lipman, 2015). Atkinson et al. (2014), Dennenberg and Curtiss (2016), and Lipman (2015) advocate the education of healthcare providers on the existence and effectiveness of the pain treatment alternatives. Atkinson et al. (2014) and Dennenberg and Curtiss (2016) discuss alternative treatments such as acupuncture and massage that are not typically covered by insurance companies. Lipman (2015) discusses the alternatives of psychology and physical therapy that are also not always covered by insurance providers. Lipman (2015) further points out the relationships between insurance companies and their lobbying and financial political support for politicians as an additional barrier to alternative treatment coverage.

In contrast to the messages surely conveyed through lobbying and financial support from insurance companies, Guy (2018) encourages Congress to mandate treatment coverage for opioid addiction. Guy (2018) explains that Congress has the authority to enact such legislation through the Necessary and Proper Clause and the

Taxing and Spending Clause of the Affordable Care Act (ACA). According to Guy (2018), the mandated coverage of opioid addiction treatment by insurance companies is a way to get to the root of the opioid misuse and overdose problem.

McCoy and Kanter (2018) researched the financial relationships between pharmaceutical firms that have been investigated for contributing to the opioid epidemic and congressional members of the political action committees primarily responsible for addressing the opioid epidemic. Not surprisingly, the researchers found substantial ties between committee members and campaign contributions from the firms being investigated by state and federal officials (McCoy & Kanter, 2018). Clearly, the campaign contributions create an obstacle for Congressional action that might affect the profitability of these firms.

Gap in Literature

There is a substantial amount of literature dedicated to opioids and the current opioid overdose fatality epidemic. The body of knowledge is currently increasing at a rapid rate due to the urgency of the crisis. The available literature undoubtedly describes the history of opioid use, abuse, and addiction in the United States. Opioid misuse can lead to addiction and researchers have found that opioid addicts are willing to switch from prescription opioid misuse to heroin and synthetic opioid use for various reasons. Reasons include cost, availability, purity, and withdrawal symptom avoidance. Current literature has also thoroughly covered the broad topics of legislation intended to decrease opioid overdose fatalities and some of the unintended consequences of such legislation. Kentucky's PDMP is one example of the types of legislation intended to decrease the

prescription opioid fatality rate. Kentucky's PDMP was defined in HB1 in 2012. The heroin and fentanyl overdose fatality rates increased rapidly after the passage of HB1. The gap in the literature that was addressed in the current study relates to the identification and quantification of possible relationships between the implementation of Kentucky's PDMP and the documented increase in heroin and fentanyl overdose fatality rates in Jefferson County, Kentucky.

Summary

Opioid use and abuse have long been a part of American existence (Aronson, 2011; Tricky, 2018). Early uses were primarily medical, but some recreational use was reported in opium dens (Aronson, 2011; Trickey, 2018). Recent history shows a problem with abuse, overdose, and deaths related to prescription opioids. Much of the problem with prescription opioids is related to the diversion of prescription opioids to the illicit market (HHS, n.d.b; McCabe et al., 2013; Pit et al., 2018). PDMPs were implemented across the United States to monitor prescribing practices and address the problem of prescription drug diversion (Gau & Brooke, 2017; Kentucky General Assembly, 2012). Research has shown that prescription opioid abuse is a common precursor to heroin use (Cicero et al., 2014; Unick et al., 2014). One unintended consequence of PDMP that has been identified is that prescription opioid addicts will turn to heroin and illicitly manufactured synthetic opioids when the cost of prescription opioids becomes too high or when prescription opioids are no longer readily available (Mars et al., 2014). The switch from abusing prescription opioids to heroin and synthetic opioid use carries with it a multitude of social, economic, and political implications (Dubois et al., 2016; Fudin,

2015; Fujii et al., 2018; Gau & Brooke, 2017; Gibson, 2018; Guevremont et al., 2017; Litton, 2018; McDonald et al., 2017; McLean, 2017; Pit et al., 2018; Trickey, 2018; Meyer et al., 2014; Smith, 2018; White et al., 2016).

I addressed the gap in the literature by researching the possible relationships between PDMP implementation in Kentucky with the documented increase in heroin and synthetic opioid overdose rates. Using the methodology described in Chapter 3 advanced the knowledge in this area and helped to fill the literature gap.

Chapter 3: Methodology

Introduction

Chapter 3 includes the methodology that was used to explore the possible relationships between the passage of HB1 and a documented increase in heroin and synthetic opioid overdose fatality rates. Discovering and quantifying the possible relationships was the purpose of this study. In this chapter, I address the research design and rationale as well as the data analysis, and validity of the study.

In this quantitative study, I used a quasi-experimental research design to identify and quantify the possible relationships between the passage of Kentucky's HB1 and a documented increase in heroin and synthetic opioid overdose fatalities in Jefferson County, Kentucky.

Cost and availability of opioids play roles in the decision to switch from prescription opioid misuse to heroin use (Ciccarone, 2009; Unick et al., 2014). Kentucky's HB1 was passed in 2012 with the intent of reducing the availability of prescription drugs for diversion to illicit use. This research focused on the availability of prescription opioids, heroin and synthetic opioids, to discover if the supply of both types of opioids created an environment conducive to encouraging prescription opioid misusers to choose to make the switch to heroin and synthetic opioid use. With the implementation of HB1, prescription opioid addicts might have been faced with the choice of stopping opioid misuse or switching to an available alternative.

First, reviews of LMPD arrest records were conducted to see if the implementation of HB1 influenced supply and demand related variables. For the purpose

of this study, supply and demand variables were arrest rates for trafficking and possession of prescription opioids, heroin, and synthetic opioids. Next, an interrupted time series study was conducted to see if HB1 had the intended effect of reducing prescribing rates for opioids. Additionally, interrupted time series studies were conducted to see if HB1 influenced death rates for prescription opioids, heroin, and synthetic opioids. Finally, an interrupted time series study was conducted to identify and quantify possible relationships between prescribing rates and opioid overdose death rates.

Variables

There were five primary objectives for this study. First, prescribing data were analyzed to reveal whether prescribing rates were reduced, as desired, by the intervention HB1. Second, opioid overdose fatality rates were analyzed to reveal whether the implementation of HB1 had an effect on opioid-related fatalities. Third, arrest data were analyzed to discover the supply and demand conditions for prescription and synthetic opioids in Jefferson County, Kentucky prior to and after the passage of Kentucky's HB1. Fourth, prescribing rates and opioid overdose fatality rates were analyzed to identify possible relationships. Finally, prescribing rates and supply and demand variables were analyzed to identify and quantify possible relationships.

Objective one was met using an interrupted time series study in which the independent variable was time. The year 2012, in which Kentucky's HB1 was implemented, acted as the point in time that the intervention, HB1, was introduced. The dependent variable used for objective one was prescribing rates for Jefferson County, Kentucky.

Objective two was met using an interrupted time series study in which the independent variable was also time. 2012 again acted as the point in time that the intervention, HB1, was introduced. The dependent variable for objective two was prescription opioid overdose fatality rates, heroin overdose fatality rates, and synthetic opioid overdose fatality rates.

Objective three was also met using an interrupted time series study. Again, time was the independent variable and 2012 was the point in time when the intervention, HB1, was introduced. Dependent variables were arrest rates for possession and trafficking of prescription opioids, arrest records for possession and trafficking of heroin, and possession and trafficking of synthetic opioids.

Objective four was met using interrupted time series analyses. Opioid prescribing rates were used as the independent variable. The dependent variables for meeting objective four were prescription opioid overdose fatality rates, heroin overdose fatality rates, and synthetic opioid overdose fatality rates.

Objective five was met using bivariate regression analyses. Opioid prescribing rates were the independent variable. The dependent variables for meeting objective five were arrest records for possession and trafficking of prescription opioids, possession and trafficking of heroin, and possession and trafficking of synthetic opioids.

Research Design

I used interrupted time series studies to identify possible effects of the implementation of Kentucky's HB1. The years prior to 2012 established a baseline for comparison. The comparison clarified trends prior to and following 2012, the year that

Kentucky's HB1 was passed into law. The interrupted time series analysis was used because it allowed for the isolation of the year 2012 as a point in time when the independent variable, HB1, was introduced to the population of Kentucky. I was interested in the possible changes among dependent variables related to the heroin and synthetic opioid crisis in Jefferson County, Kentucky. The dependent variables were related to opioid availability, prescription opioid overdose fatality rates, and heroin and synthetic opioid overdose fatality rates over the time period between 2007 and 2017. The 10-year range includes the 5 years prior to and 5 years after the passage of HB1. The 10-year period included sufficient time before and after the introduction of HB1 to identify any pre-HB1 trends to be compared with post-HB1 trends. Identification of trends helped to understand the possible relationships between the passage of HB1 and the recent documented increase in heroin and synthetic opioid overdose rates.

Target Population

Inclusion in this study was based on inclusion in various publicly available databases. Each database focuses on the geographical area of Jefferson County, Kentucky.

The availability of both prescription opioids and heroin and synthetic opioids was measured using the Louisville Metro Police Department's arrest records database. The database is available on the Louisville Metro Police Department public website. Arrest record data was helpful with understanding both the availability of and demand for illicit prescription opioids and heroin and other synthetic opioids.

The target population for primary objective one of this study, determining the supply and demand environment in Jefferson County, Kentucky before and after the passage of HB1, was drawn from the Louisville Metro Police Department web page, https://data.louisvilleky.gov/dataset/crime-reports. Each year was selected and filtered to reveal arrests for the following violations:

- Importing Heroin
- Possession of a Controlled Substance – 1st Degree - 1st Offense - Heroin
- Possession of a Controlled Substance - 1st Degree – 2nd Offense - Heroin
- Possession of a Controlled Substance – 1st Degree – 3rd or > Offense - Heroin
- Possession of a Controlled Substance – 1st Degree – 1st Offense - Opiates
- Possession of a Controlled Substance – 2nd Offense – Opiates
- Possession of a Controlled Substance-1st Degree 3rd or > Offense – Opiates
- Possession of a Controlled Substance – 2nd Degree - Codeine
- Trafficking a Controlled Substance – 1st Degree – 1st Offense (< 10 DU Opiates)
- Trafficking a Controlled Substance – (> or = 10 DU Opiates)
- Trafficking a Controlled Substance – 1st Degree -1st Offense - Heroin (> or = 2 Grams but < 100G)
- Trafficking a Controlled Substance – 1st Degree – 1st Offense (< 2 Grams - Heroin)
- Trafficking a Controlled Substance – 1st Degree – 2nd or > Offense (< 2 Grams - Heroin)

- Trafficking a Controlled Substance – 1st Degree – 2nd or > Offense (> or = 2 Grams - Heroin)
- Aggravated Trafficking in a Controlled Substance - 1st Degree (> or = 100 Grams - Heroin)
- Trafficking a Controlled Substance – 1st Degree – 2nd or > Offense (< 10 DU Opiates)
- Trafficking a Controlled Substance – 1st Degree – 2nd or > Offense (> or = 10 DU Opiates)
- Trafficking a Controlled Substance – 2nd Degree-1st Offense (> or = 10 DU Codeine)
- Trafficking a Controlled Substance – -2nd Degree – 1st Offense (< 10 DU Codeine)
- Trafficking a Controlled Substance – 2nd Degree – 2nd or > Offense (> or = 10 DU Codeine)
- Trafficking a Controlled Substance – 1st Degree – 1st offense (< 2 Grams Fentanyl)
- Trafficking a Controlled Substance – 1st Degree – 2nd Offense or > (> Or = 2 Grams - Fentanyl)
- Trafficking a Controlled Substance –, 1st Degree – 2nd Offense or > (< 2 Grams Fentanyl)

The target population for primary objective two of this study, determining and quantifying possible relationships between the passage of HB1 and a documented

increase in heroin and synthetic opioids, was people who have died in Jefferson County, Kentucky due to opioid-related overdose. The sample was drawn from CDC archives found at https://www.wonder.cdc.gov. The "Multiple Causes of death (Detailed Mortality)" link listed under the heading "Mortality" was clicked to open a page containing search by date options. The data request link in the "1999-2017" category was clicked, and the terms of use agreement page was activated.

For section one, the group results were filtered by state and county. For section two, the state of Kentucky was highlighted, and the "open" button selected to reveal and select "21111 (Jefferson County, KY)." All categories remained selected in the 2013 Urbanization selection box. For section three, all categories remained with the default selections of "All Ages," "All Genders," "All Origins," and "All Races."

There were multiple entries for section four due to the fact that there were multiple years examined in this study. The individual years from 2007 through 2017 were input into section four to obtain a data set for each year.

The section five boxes remained with their default selections of "All Weekdays," "All Values," and "All Places." For section six, the "UCD – ICD-10 Codes" radio button and "*All* (All Causes of Death) remained selected.

Section seven was changed several times to include the various categories of opioids as the cause of death. The values of T-40.0 (Opium), T-40.1 (Heroin), T-40.2 (Other Opioids), T-40.3 (Methadone), T-40.4 (Other Synthetic Narcotics) were used individually in separate searches to obtain data for the various opioid-related causes of death for each year included in this study.

Data Analysis Plan

SPSS was used to employ interrupted time series analyses. Prescribing rates for Jefferson County, Kentucky, as reported by the CDC's (n.d.) U.S. Opioid Prescribing Rate Maps, were entered into SPSS along with prescription opioids death rates and heroin and synthetic opioid death rates. Interrupted time series analyses quantified possible relationships between the prescribing rates and opioid mortality rates.

Opioid death statistics for Jefferson County Kentucky were further entered into SPSS to quantify possible effects of implementing Kentucky's HB1. Data were collected from the online database published by CDC Wonder (Centers for Disease Control and Prevention, n.d.). The analyses measured the possible effects that the intervention, HB1, had on opioid prescribing rates as well as prescription opioid and heroin and synthetic opioid overdose fatality statistics. Opioid overdose fatality rates for the years between 2007 and 2017 were entered to indicate changes in fatality rates after the passage of HB1and infer possible relationships between both variables.

Threats to Validity

Although attempts were made to include all pertinent data into this study, it was unavoidable that some data were missing. This lack of data could pose a significant threat to the validity of objective one in this study. The dataset that was compiled for objective one of this study comes from published police arrest statistics. While this might be a valid way to collect data concerning the supply and demand for specific drugs, the database is lacking in some ways. First, the data only measure the number of people who were charged with one of the multiple crimes indicating a supply or demand for opioids. The

data set fails to recognize the multitude of people who are never arrested or charged with violating the statutes. Furthermore, some of the charges listed in the data set are vague. This vagueness makes it impossible to determine an exact number for each violation of law concerning opioids. For example, there are many people charged with Possession of a Controlled Substance. This leaves out the indication of which type of controlled substance that was allegedly possessed. Therefore, the statistics for these charges must be left out of the current study.

Ethical Procedures

All data were collected from publicly accessible website databases. No personal identification of anyone included in the sample can be made using the data included in this study. The Louisville Metro Police Department webpage contains both the date of arrest and address of arrest. Date of arrest and address of arrest could arguably be used to narrow identification of arrested subjects, but this data will not be included in the current study.

Summary

I explored the possible relationships between the passage of HB1 and recent documented increases in heroin and synthetic opioid overdose deaths.

This research was guided by the following research questions:

1. Did the implementation of Kentucky's HB1 change the rate of heroin and fentanyl overdose fatalities in Jefferson County, Kentucky?
    a. Have opioid prescribing rates decreased after the implementation of Kentucky's HB1?

b. Have arrest rates for possession of heroin and synthetic opioids increased after the implementation of Kentucky's HB1?
c. Have arrest rates for trafficking of heroin and synthetic opioids increased after the implementation of Kentucky's HB1?
d. Is there a statistically significant difference in the opioid prescribing rate after the implementation of HB1?
e. Is there a statistically significant difference in the prescription opioid overdose fatality rate after the implementation of HB1?
f. Is there a statistically significant difference in the heroin and synthetic opioid overdose fatality rate after the implementation of HB1?
g. Is there a statistically significant relationship between prescribing rates and heroin and synthetic opioid overdose fatality rates?

I used quantitative time series analyses methods to explore the possible relationships. All data were collected from publicly accessible website databases that do not contain personal identifiable information. The results of this study can be used to guide future drug legislation and avoid unintended consequences that may prove deadly for a large portion of the population. The positive social implication for this study is that the results could ultimately save lives.

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

Introduction

The purpose of this study was to identify and quantify the possible relationships between the passage of HB1 and a documented increase in heroin and synthetic opioid overdose fatalities. The research was guided by the following research questions:

1. Did the implementation of Kentucky's HB1 change the rate of heroin and fentanyl overdose fatalities in Jefferson County, Kentucky?
    a. Have opioid prescribing rates decreased after the implementation of Kentucky's HB1?
    b. Have arrest rates for possession of heroin and synthetic opioids increased after the implementation of Kentucky's HB1?
    c. Have arrest rates for trafficking of heroin and synthetic opioids increased after the implementation of Kentucky's HB1?
    d. Is there a statistically significant difference in the opioid prescribing rate after the implementation of HB1?
    e. Is there a statistically significant difference in the prescription opioid overdose fatality rate after the implementation of HB1?
    f. Is there a statistically significant difference in the heroin and synthetic opioid overdose fatality rate after the implementation of HB1?
    g. Is there a statistically significant relationship between prescribing rates and heroin and synthetic opioid overdose fatality rates?

The null hypothesis for this study was that there is no relationship between Kentucky's HB1 and the documented increase in heroin and synthetic opioid overdose rates. The alternative hypothesis was that there is a significant relationship between the passage of Kentucky's HB1 and the documented increase in heroin and synthetic opioid overdose rates. In Chapter 4, I outline the data collection procedures and results of the analyses. I describe the collection of secondary data for this study and discuss the analyses conducted for each research question, as well as the results of the individual analyses.

Data Collection

There were three sources for the data used in this study. First, data concerning opioid prescribing rates for Jefferson County, Kentucky were drawn from the CDC's (n.d.) U.S. Opioid Prescribing Rate Maps. The CDC reports prescribing rate data for the years of 2006 through 2017. I used data from 2007 through 2017.

Second, data concerning arrests for possession and trafficking of opioids were drawn from the Louisville Metro Police Department's (LMPD, n.d.) crime reports. LMPD reports arrest data between the years of 2003 through 2019. I used arrest data from 2007 through 2017.

Finally, data concerning opioid overdose fatalities were drawn from the CDC (n.d.) Wonder database. The database houses information about fatalities in the U.S. CDC Wonder database searches can be filtered to pinpoint specific causes of death. I used opioid overdose fatality data from 2007 through 2017.

All three databases are available to the general public on the Internet. No demographic information, such as age or sex, were used in this study. I was concerned with statistical significance between a specific public policy and overall fatality rates. Therefore, no demographic data was needed.

The population for this study included all residents of Jefferson County, Kentucky during the years from 2007 to 2017. The mandates in HB1 apply equally to all residents of Kentucky. To be included in this study, residents of Jefferson County must have either died from an opioid overdose or been arrested for possession or trafficking of opioids.

Results

Research Question 1a: Have Opioid Prescribing Rates Decreased After the Implementation of Kentucky's HB1?

A visual inspection of the related data revealed that there was a decrease in opioid prescribing rates in Jefferson County, Kentucky after the implementation of HB1. As can be seen in Figure 1, opioid prescribing rates in Jefferson County, Kentucky peaked in 2008 with 136.5 prescriptions per 100 U.S. residents. This statistic indicates that some Jefferson County residents received multiple opioid prescriptions throughout 2008. The number of residents receiving prescriptions is not clear because the CDC only reports the overall prescription rate. It is also unclear how many prescriptions, on average, each patient received. Prescribing rates had begun to decrease in 2011 but not as dramatically as in 2012, the year that HB1 was implemented, and the following years. Opioid prescribing rates continued to decrease following the passage of HB1 in 2012. Opioid prescribing rates have decreased after the implementation of Kentucky's HB1. The opioid

prescribing rate in Jefferson county initially decreased from 130.8 prescriptions per 100 U.S. residents to 114.3 prescriptions per 100 U.S. residents in 2012. The downward trend slowed but continued from 2012 through 2017, when the prescribing rate in Jefferson County was 76.5 prescriptions per 100 U.S. residents.

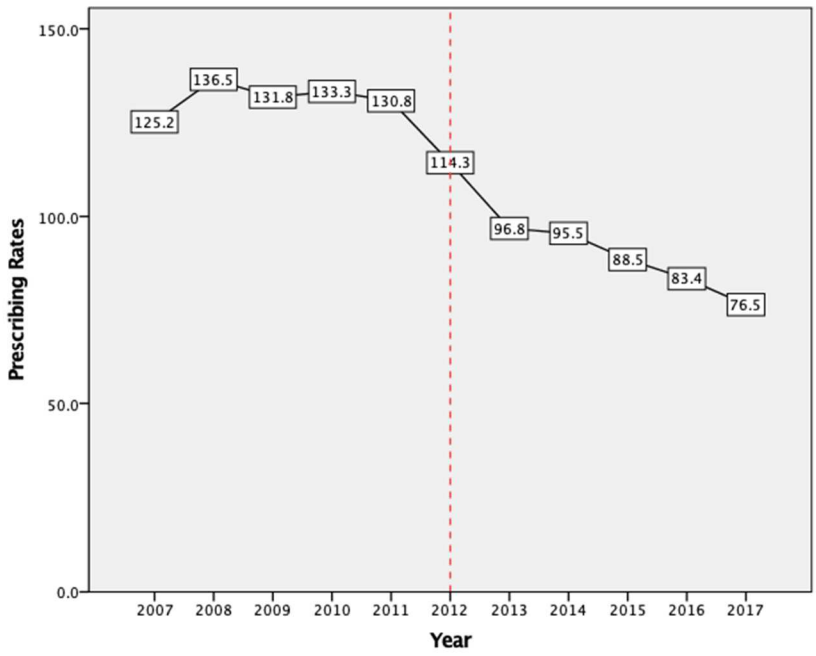

Figure 1. Yearly prescribing rates for Jefferson County, Kentucky.

Research Question 1b: Have Arrest Rates for Possession of Heroin and Synthetic Opioids Increased After the Implementation of Kentucky's HB1?

As can be seen in Figure 2, arrest rates for possession of heroin and synthetic opioids peaked in 2016 with 1381 arrests. Arrest rates had shown an increase but had remained relatively stable between 2007 and 2011. The arrest rate for possession of heroin and synthetic opioids increased from 107 arrests in 2006 to 436 in 2012, the year that HB1 was implemented. The arrest rate continued to increase until it peaked at 1,381

arrests in 2016. This increase indicates a dramatic rise in demand for heroin and synthetic opioids beginning in 2012, the year that HB1 was implemented.

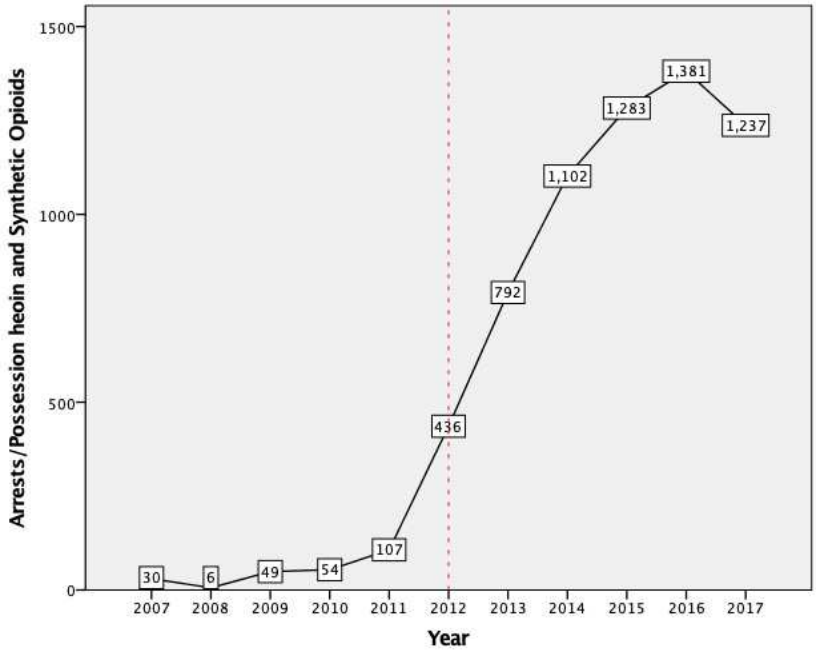

Figure 2. Jefferson County arrests for possession of heroin and synthetic opioids.

Research Question 1c: Have arrest rates for trafficking of heroin and synthetic opioids increased after the implementation of Kentucky's HB1?

As can be seen in Figure 3, trafficking in heroin and synthetic opioids peaked in 2016 with 372 arrests. Prior to 2012 the arrest rates for trafficking of heroin and synthetic opioids increased slightly but remained relatively stable. The arrest rate for trafficking of heroin and synthetic opioids in Jefferson County, Kentucky increased from 46 arrests in 2011 to 147 arrests in 2012, the year that HB1 was implemented. Arrest rates for trafficking of heroin and synthetic opioids continued to increase from 147 arrests in 2012

until the arrest rate peaked in 2016 at 372 arrests. This increase indicates a rise in supply of heroin and synthetic opioids in Jefferson County, Kentucky beginning in 2012.

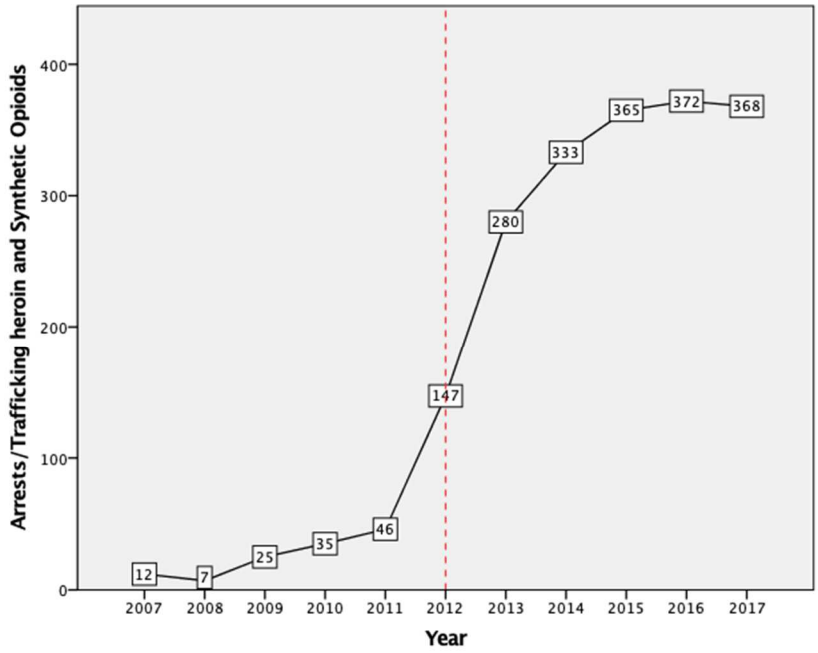

Figure 3. Jefferson County arrests for trafficking heroin and synthetic opioids.

Research Questions 1d Through 1g

For research questions 4 through 7, data of three variables from 2007 to 2017 (See Table 1) were retrieved from the CDC.

- Prescribing rate: Prescribing rate contains data that was collected from the CDC prescribing rate maps at https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html . The prescribing rate represents retail opioid prescriptions dispensed per 100 persons per year.

- Mortality of opioids: Mortality of prescription opioids contains data from the CDC Wonder database concerning the number of prescription opioid deaths per year in Jefferson County, Kentucky.
- Mortality of heroin and synthetic opioids: Mortality of heroin and synthetic opioids contains data from the CDC Wonder database concerning the number of heroin and synthetic opioid deaths per year in Jefferson County, Kentucky.

Note that the intervention, Kentucky's HB1, was passed in February of 2012.

The purpose of research questions 4 through 7 was two-fold. First, to determine the effect of the intervention on the three outcome measures (Prescribing rate, mortality of opioids, and mortality of heroin and synthetic opioids; Objective 1). Second, to determine the relationships between the two mortality measures (mortality of opioids and mortality of heroin and synthetic opioids) and prescribing rate (Objective 2).

Table 1.

Data of the Study

Year	Prescribing rate	Mortality of opioids	Mortality of heroin and synthetic opioids
2007	125.2	0	0
2008	136.5	11	0
2009	131.8	18	0
2010	133.3	19	0
2011	130.8	52	12
2012	114.3	41	37
2013	96.8	34	62
2014	95.5	39	39
2015	88.5	27	87
2016	83.4	54	177
2017	76.5	69	275

Analysis Methods

Research questions 1a through 1c were analyzed by simply reviewing the data listed in the CDC's (n.d.) prescribing rate maps and the LMPD online arrest database. Research questions 1a through 1c are as follows:

1a. Have opioid prescribing rates decreased after the implementation of Kentucky's HB1? Research question 1a was analyzed by reviewing the CDC's (n.d.) prescribing rate maps.

1b. Have arrest rates for possession of heroin and synthetic opioids increased after the implementation of Kentucky's HB1? Research question 1b was analyzed by reviewing the LMPD's (n.d.) arrest statistics for the years of 2007 through 2017.

1c. Have arrest rates for trafficking of heroin and synthetic opioids increased after the implementation of Kentucky's HB1? Research question 1c was also analyzed by reviewing the LMPD's (n.d.) arrest statistics for the years of 2007 through 2017.

Research Questions 1d Through 1g

Data were imported into and analyzed using SPSS version 23 for Windows (IBM Corp., Armonk, NY). Time-series analysis is used when observations are made repeatedly over a period of time. The time series model used in this study was auto-regressive, integrated, moving average, called ARIMA (*p, d, q*) model. The auto-regressive element, *p*, represents the lingering effects of the preceding scores. The integrated element, *d*, represents trends in the data, and the moving average element, *q*, represents the lingering effects of preceding random shocks (Yaffee and McGee, 2000; Tabachnick and Fidell, 2013).

Time series may be stationary or nonstationary (Yaffee and McGee, 2000). Nonstationary series have systematic trends (ex: linear and quadratic), while a stationary process has a constant mean and variance over the time period of the study (Tabachnick and Fidell, 2013). For ARIMA models, the time series need to be stationary (Yaffee and McGee, 2000). The middle element, *d*, should hence be investigated before *p* and *q*. The goal is to determine if the process is stationary and, if not, to make it stationary before determining the values of *p* and *q*. For each study variable (Prescribing rate, mortality of

opioids, and mortality of heroin and synthetic opioids), stationarity was examined by investigating the figure of the sequence over the time period, and the figures of autocorrelation functions (ACFs) and partial autocorrelation functions (PACFs). Autocorrelations are self-correlations of the series of scores with itself, removed one or more periods in time (Tabachnick and Fidell, 2013). In other words, the ACF show the correlation in a series between one observation and another observation in the same series *k* lags away (Yaffee and McGee, 2000). Partial autocorrelations are self-correlations with intermediate autocorrelations partialed out (Tabachnick and Fidell, 2013). The PACF, when working at *k* lags, controls for the confounding autocorrelations in the intermediate lags, with the purpose of partial out those autocorrelations, leaving only the autocorrelation between the current and k^{th} observation (Yaffee and McGee, 2000).

If a series is stationary, the line of the sequence over the time period will be basically horizontal with constant variance and the magnitude of the autocorrelation attenuates fairly rapidly, whereas if the series is nonstationary, the line will not be horizontal with constant variance and the autocorrelation diminishes gradually or demonstrates wild fluctuation before it drops below the level of significance (Yaffee and McGee, 2000; Tabachnick and Fidell, 2013; IBM Corp., 2015). Differencing (i.e., subtracting the value of an earlier observation from the value of a later observation) was undertaken if the time series was not stationary (Tabachnick and Fidell, 2013). For nonstationary series, *d*-values of 1 or 2 are usually adequate to make the mean stationary (Tabachnick and Fidell, 2013).

The basic processes of the ARIMA (*p, d, q*) model include the autoregressive process (*p*), the integrated process (*d*), and the moving average process (*q*). After ensuring the series are stationary, the next step is identification in which ACFs and PACFs are examined to see which of the potential patterns are present in the data for the autoregressive process and the moving average process (Yaffee and McGee, 2000; Tabachnick and Fidell, 2013; IBM Corp., 2015). The general guidelines for identifying the process are:

- Autoregressive processes have an exponentially declining ACF and spikes in the first one or more lags of the PACF. The number of spikes indicates the order of the autoregression (*p*).
- Moving average processes have spikes in the first one or more lags of the ACF and an exponentially declining PACF. The number of spikes indicates the order of the moving average (*q*).
- Mixed processes typically show exponential declines in both the ACF and the PACF.

In addition to the guidelines for identifying the ARIMA processes, the Expert Modeler modeling procedure in SPSS (IBM Corp., 2015) was used to find the initial best fitting ARIMA model for each dependent series (Penfold and Zhang, 2013).

Analysis Methods for Objective 1

Research questions 1d through 1f. Research questions 1d through 1f were analyzed using interrupted time series methods. Research questions 1d through 1f are as follows:

1d. Is there a statistically significant difference in the opioid prescribing rate after the implementation of HB1?

1e. Is there a statistically significant difference in the prescription opioid overdose fatality rate after the implementation of HB1?

1f. Is there a statistically significant difference in the heroin and synthetic opioid overdose fatality rate after the implementation of HB1?

Interrupted time-series (ITS) analysis (Wagner, Soumerai, Zhang, & Ross-Degnan, 2002; Penfold and Zhang, 2013) was conducted to determine the effect of the intervention on the three outcome measures (Prescribing rate, mortality of opioids, and mortality of heroin and synthetic opioids) (Objective 1). There were three dependent variables, including prescribing rate, mortality of opioids, and mortality of heroin and synthetic opioids, and one independent variable, the intervention. Equation 1 presents the time series regression equation:

$$Y_t = \beta_0 + \beta_1 * T_{1t} + \beta_2 * I_t + \beta_3 * T_{2t} + e_t \quad \text{..... (Equation 1)}$$

where

- Y_t is the outcome variable in year t;
- T_{1t} is a continuous variable indicating time in year at time t from the start of the observation period (T_1 = 1, 2, …, 11);
- I_t is an indicator variable equal to 0 before the intervention and equal to 1 after the intervention;
- T_{2t} represents time after intervention, equal to 0 before the intervention and equal to the number of months after the intervention;

- The error term e_t represents the random error not explained by the model, consisting of normally distributed random error and an error at time t that may be correlated to errors at preceding time points.

Table 2 presents the example data format for the ITS analysis. Coefficient β_0 estimated the yearly value of the outcome variable at baseline (2007); β_1 estimated the baseline slope parameter representing change in the outcome variable that occurred every year before the intervention; β_2 was change in the outcome variable immediately after the intervention (intercept changes); β_3 estimated yearly change in outcome variable compared with trend before the intervention (slope changes). Thus, sum of β_1 and β_3 was the post-intervention slope.

Table 2.

Example Data Format for ITS Analysis

Year	Prescribing rate (Y_t)	Time (T_{1t})	Intervention (I_t)	Time after intervention (T_{2t})
2007	125.2	1	0	0
2008	136.5	2	0	0
2009	131.8	3	0	0
2010	133.3	4	0	0
2011	130.8	5	0	0
2012	114.3	6	1	1
2013	96.8	7	1	2
2014	95.5	8	1	3
2015	88.5	9	1	4
2016	83.4	10	1	5
2017	76.5	11	1	6

Analysis Methods for Objective 2

Research question 1g. Is there a statistically significant relationship between prescribing rates and heroin and synthetic opioid overdose fatality rates?

Objective 2 was to determine the relationships between the two mortality measures (mortality of opioids and mortality of heroin and synthetic opioids) and prescribing rate. ARIMA models with mortality of opioids and mortality of heroin and synthetic opioids as the dependent variables and prescribing rate as the independent variable were performed.

Assumptions of Time-Series Analysis

For each analysis performed, the following assumptions of time-series analysis were examined (Yaffee and McGee, 2000; Tabachnick and Fidell, 2013).

- Normality of residuals: Normality of the residuals was checked using the Shapiro-Wilk normality tests. The Shapiro–Wilk test examines the null hypothesis that a sample came from a normally distributed population (Moore et al., 2009). A *p* value less than 0.05 indicates that the null hypothesis should be rejected and there is enough evidence to claim that the data tested are not from a normally distributed population, i.e., the data are not normal. On the contrary, if the *p* value is greater than 0.05, then the null hypothesis that the data came from a normally distributed population cannot be rejected, and hence there is not enough evidence to claim that the data tested are not from a normally distributed population, i.e., the data are normal.
- Homogeneity of variance and zero mean of residuals: Plots of standardized residuals versus predicted values were used to assess homogeneity of variance over time. This assumption would be satisfied if the data points were randomly distributed around the 0-horizontal line.
- Independence of residuals: ACFs and PACFs for the residuals were used to examine this assumption. Once the model is developed and residuals are computed, there should be no remaining autocorrelations or partial autocorrelations at various lags in the ACFs and PACFs. The Ljung-Box Q (LBQ) statistics were used to test the null hypothesis that autocorrelations up to lag *k*

equal zero (that is, the data values are random and independent up to a certain number of lags). In addition, figures of the ACFs and the PACFS were checked to ensure that all ACFs and PACFs were within the 95% confidence bounds (an indication of no significant autocorrelations or partial autocorrelations)

If any of the assumptions were violated, different ARIMA models (ex: ARIMA (1,1,0)) were performed, and results were examined and compared to the initial ARIMA (0,1,0) model. For any analysis, a *p* value less than 0.05 was considered significant.

Analysis Results

Figures 4-6 are the plots of the three study variables, including, prescribing rate, mortality of opioids, and mortality of heroin and synthetic opioids, between 2007 and 2017. For prescribing rate, the mean seemed edging downwards, whereas for the two mortality measures, the means seemed going upwards. As the mean was changing for each variable, the series may not be stationary, and the trend may be removed by differencing.

Table 3 and Figures 7-9 present the ACFs and PACFs for the three time series variables. For prescribing rate, the autocorrelation diminished gradually; for mortality of opioids and mortality of heroin and synthetic opioids, the autocorrelation demonstrated some fluctuation over time. These may be indications that the series were not stationary. Based on the results of sequence plots, ACFs, and PACFs, all three series were differenced once ($d = 1$) to remove the trend.

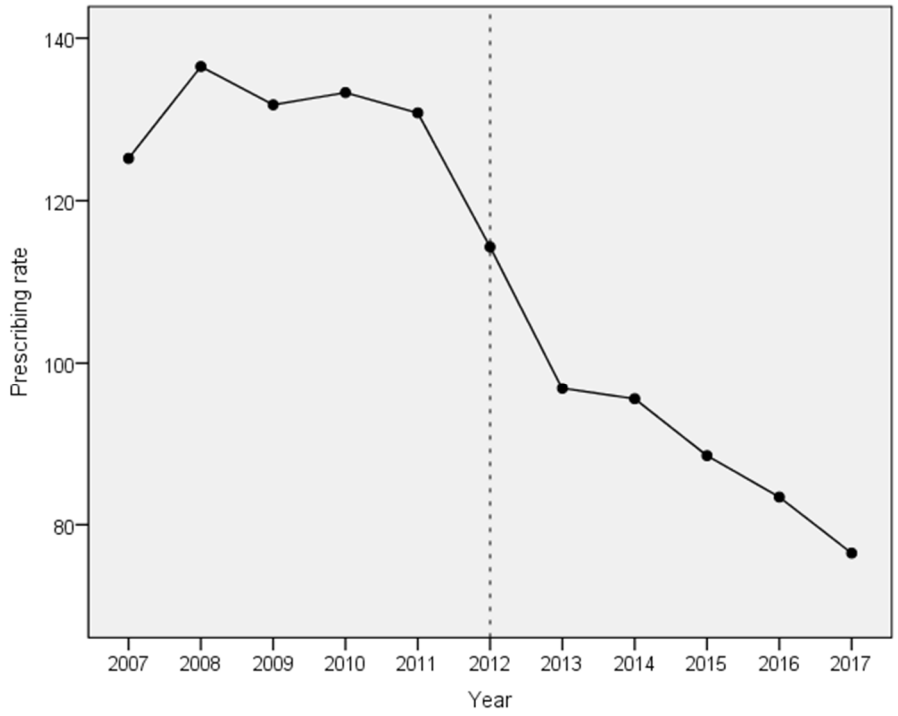

Figure 4. Sequence of prescribing rate over time (The dash line represents the occurrence of the intervention).

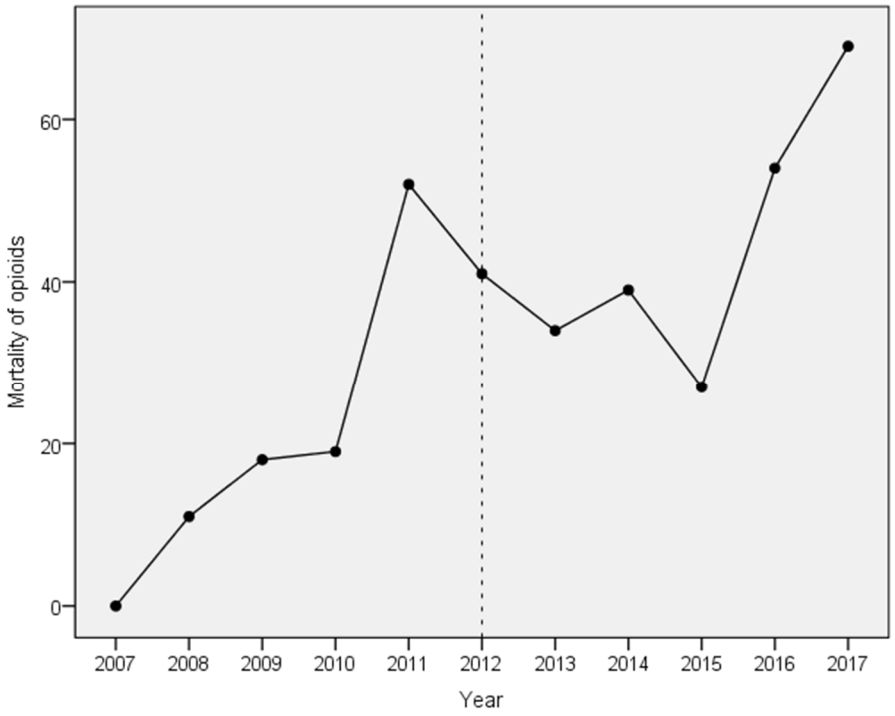

Figure 5. Sequence of mortality of opioids over time (The dash line represents the occurrence of the intervention).

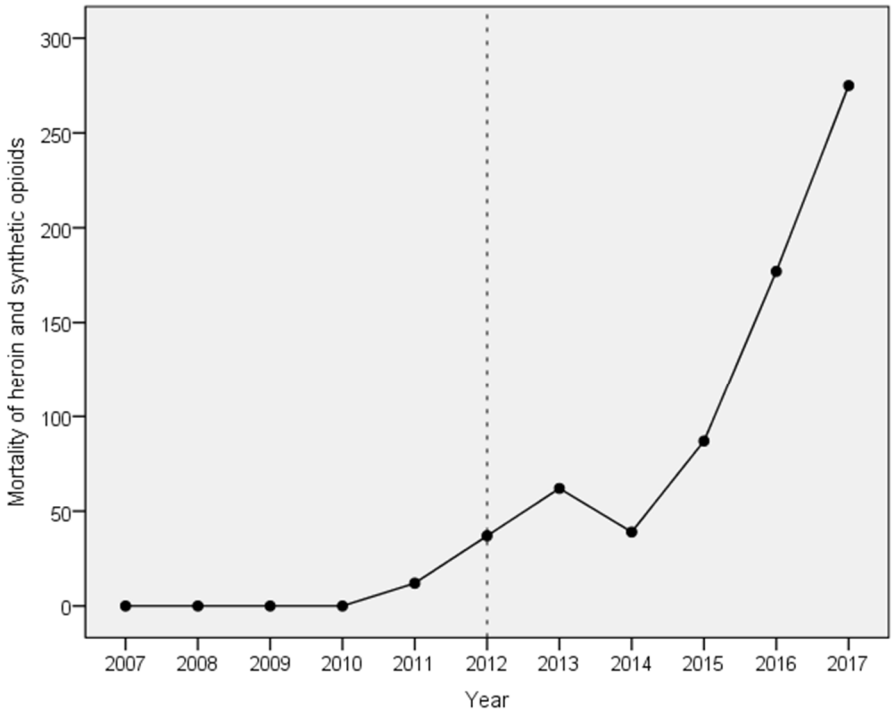

Figure 6. Sequence of mortality of heroin and synthetic opioids over time (The dash line represents the occurrence of the intervention).

Table 3.

ACFs and PACFs for the Three Time Series Variables

				Box-Ljung Statistic				
DV	Lag	Autocorrelation	SE	Value	*df*	*p*	Partial autocorrelation	*SE*
1	1	.781	.302	8.725	1	.003	.781	.302
	2	.502	.449	12.732	2	.002	-.277	.302
	3	.222	.498	13.616	3	.003	-.173	.302
	4	-.063	.507	13.696	4	.008	-.247	.302
	5	-.354	.507	16.690	5	.005	-.326	.302
	6	-.467	.529	22.916	6	.001	.154	.302
	7	-.423	.566	29.313	7	.000	.132	.302
	8	-.346	.594	35.022	8	.000	-.105	.302
	9	-.254	.612	39.618	9	.000	-.117	.302
2	1	.416	.302	2.477	1	.115	.416	.302
	2	.089	.350	2.604	2	.272	-.102	.302
	3	.050	.352	2.648	3	.449	.063	.302
	4	-.193	.353	3.406	4	.492	-.283	.302
	5	.093	.362	3.613	5	.606	.393	.302
	6	.075	.364	3.773	6	.707	-.256	.302
	7	-.209	.366	5.330	7	.620	-.133	.302
	8	-.190	.376	7.045	8	.532	-.177	.302
	9	-.351	.385	15.864	9	.070	-.140	.302
3	1	.547	.302	4.272	1	.039	.547	.302
	2	.201	.381	4.914	2	.086	-.140	.302
	3	.054	.391	4.966	3	.174	.007	.302
	4	.026	.391	4.979	4	.289	.024	.302
	5	-.123	.391	5.340	5	.376	-.208	.302
	6	-.229	.395	6.841	6	.336	-.096	.302
	7	-.262	.407	9.297	7	.232	-.096	.302
	8	-.281	.422	13.063	8	.110	-.146	.302
	9	-.262	.439	17.954	9	.036	-.062	.302

Note: For *DV* (dependent variable), 1 = Prescribing rate, 2 = Mortality of opioids, and 3 = Mortality of heroin and synthetic opioids. *SE* = standard error, *df* = degrees of freedom, *p* = *p* value.

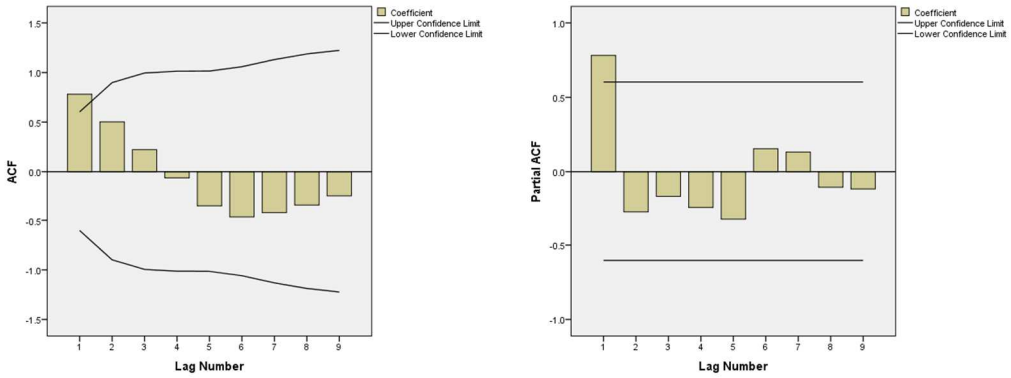

Figure 7. Figures of ACFs (right) and PACFs (left) for prescribing rate.

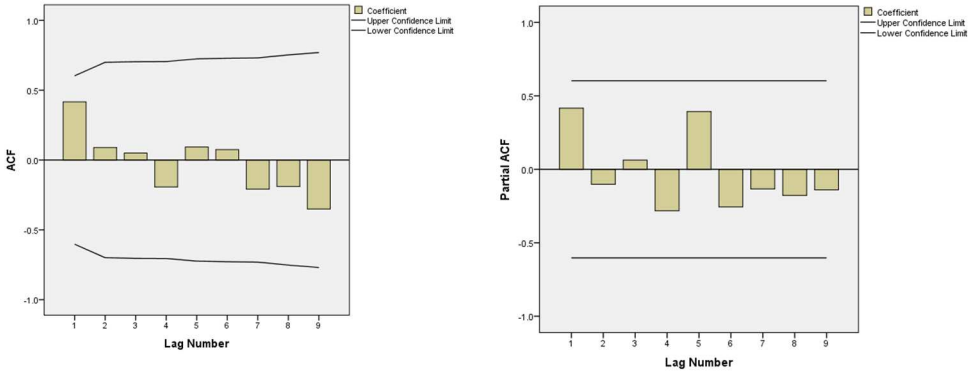

Figure 8. Figures of ACFs (right) and PACFs (left) for mortality of opioids.

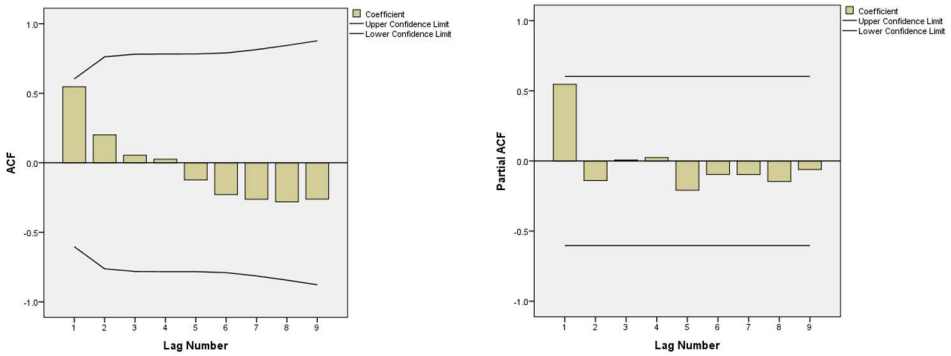

Figure 9. Figures of ACFs (right) and PACFs (left) for mortality of heroin and synthetic opioids.

Table 4 presents the three measures of the study (original scale and lag 1 differences). Figures 10-12 are the plots of the lag 1 differences of the three study variables, including, prescribing rate, mortality of opioids, and mortality of heroin and synthetic opioids, against time. The three measures appeared to be more stationary with respect to central tendency after lag 1 differencing. Table 5 and Figures 13-15 present the ACFs and PACFs for the lag 1 differences for the three time series variables. For all three variables, the autocorrelations were fairly small and insignificant. For the prescribing rate, the autocorrelation values ranged from a low of -.311 at lag 5 to a high of .139 at lag 1. For the mortality of prescription opioids, the autocorrelation values ranged from a low of -.496 at lag 4 to a high of .209 at lag 5. For the mortality of heroin and synthetic opioids, the autocorrelation values ranged from -.294 at lag 7 to a high of .471 at lag 1. Thus, we concluded that the data were stationary after differencing once ($d = 1$).

The results of the ACFs and PACFs for the lag 1 differences of the three measures (Figures 13-15) were also used to determine if potential patterns are present in the data for the autoregressive process and the moving average process. As there were no obvious spikes or exponentially declining in the ACFs and PACFs for all three measures, it may be reasonable to set p = 0 and q = 0 for the initial ARIMA models. In other words, an ARIMA (0, 1, 0) model was identified as the initial best fitting ARIMA model for each dependent series in this study. The results for identifying the ARIMA processes using the Expert Modeler modeling procedure in SPSS confirmed the choice of the ARIMA (0, 1, 0) as the initial model for further data analysis.

Table 4.

Data of the Study (Original Scale and Lag 1 Differences)

	Prescribing rate		Mortality of opioids		Mortality of heroin and synthetic opioids	
Year	Original value	Lag 1 difference	Original value	Lag 1 difference	Original value	Lag 1 difference
2007	125.2	.	0	.	0	.
2008	136.5	11.3	11	11	0	0
2009	131.8	-4.7	18	7	0	0
2010	133.3	1.5	19	1	0	0
2011	130.8	-2.5	52	33	12	12
2012	114.3	-16.5	41	-11	37	25
2013	96.8	-17.5	34	-7	62	25
2014	95.5	-1.3	39	5	39	-23
2015	88.5	-7	27	-12	87	48
2016	83.4	-5.1	54	27	177	90
2017	76.5	-6.9	69	15	275	98

Note: Lag 1 difference was computed as "Y_t - $Y_{t-1.}$"

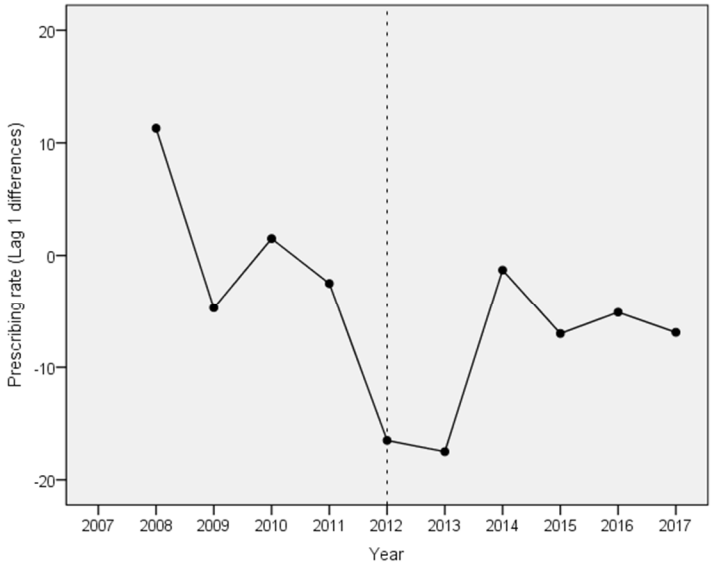

Figure 10. Sequence of prescribing rate over time (Lag 1 differences) (The dash line represents the occurrence of the intervention).

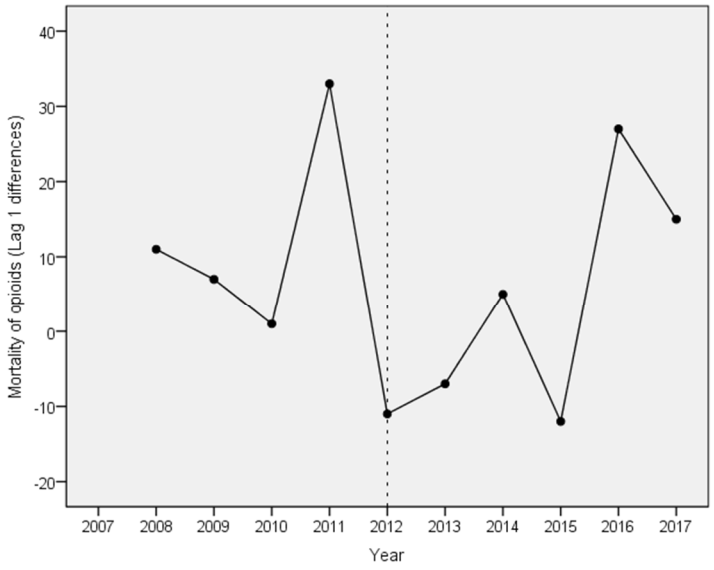

Figure 11. Sequence of mortality of opioids over time (Lag 1 differences) (The dash line represents the occurrence of the intervention).

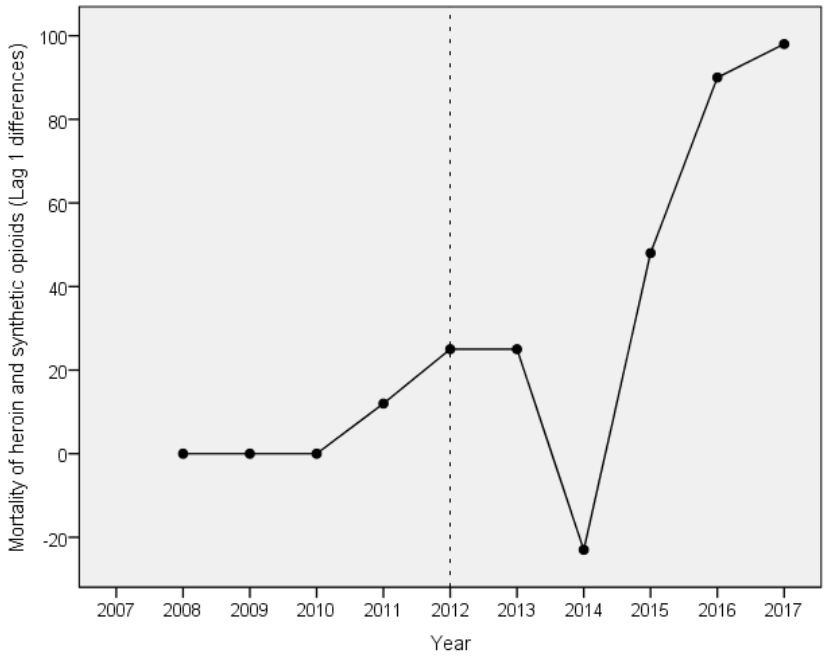

Figure 12. Sequence of mortality of heroin and synthetic opioids over time (Lag 1 differences) (The dash line represents the occurrence of the intervention).

Table 5.

ACFs and PACFs for the Three Time Series Variables (Lag 1 Differences)

				Box-Ljung statistic				
DV	Lag	Autocorrelation	*SE*	Value	*df*	*p*	Partial autocorrelation	*SE*
1	1	.139	.316	.256	1	.613	.139	.316
	2	-.019	.322	.262	2	.877	-.039	.316
	3	-.024	.322	.272	3	.965	-.017	.316
	4	-.231	.323	1.340	4	.855	-.231	.316
	5	-.311	.339	3.663	5	.599	-.267	.316
	6	.082	.366	3.865	6	.695	.151	.316
	7	-.076	.368	4.096	7	.769	-.142	.316
	8	-.007	.370	4.098	8	.848	-.032	.316
2	1	-.254	.316	.859	1	.354	-.254	.316
	2	-.083	.336	.964	2	.618	-.158	.316
	3	.087	.338	1.094	3	.778	.025	.316
	4	-.496	.340	6.006	4	.199	-.523	.316
	5	.209	.406	7.054	5	.217	-.078	.316
	6	.040	.417	7.102	6	.312	-.099	.316
	7	-.059	.417	7.243	7	.404	-.074	.316
	8	.040	.418	7.339	8	.501	-.356	.316
3	1	.471	.316	2.953	1	.086	.471	.316
	2	-.024	.380	2.962	2	.227	-.315	.316
	3	-.169	.380	3.449	3	.327	-.007	.316
	4	.061	.387	3.523	4	.474	.229	.316
	5	-.017	.388	3.530	5	.619	-.312	.316
	6	-.138	.388	4.104	6	.663	.018	.316
	7	-.294	.393	7.556	7	.373	-.223	.316
	8	-.255	.415	11.444	8	.178	-.143	.316

Note: For *DV* (dependent variable), 1 = Prescribing rate, 2 = Mortality of opioids, and 3 = Mortality of heroin and synthetic opioids. *SE* = standard error, *df* = degrees of freedom, *p* = *p* value.

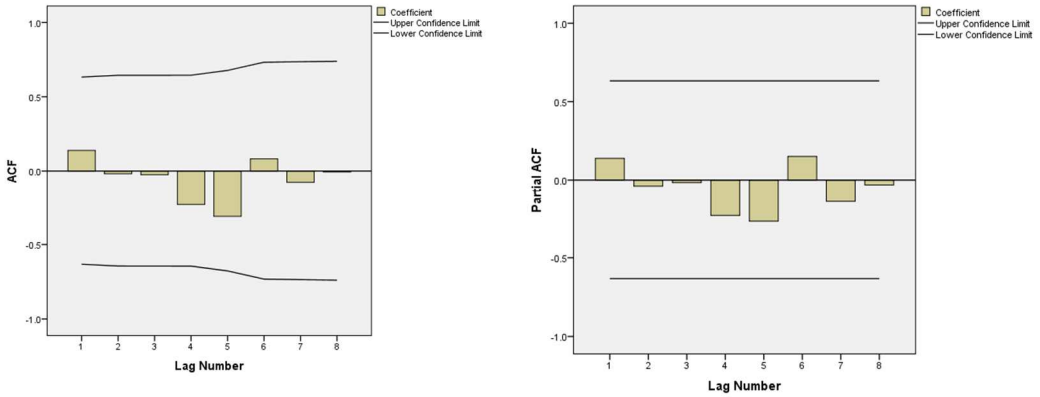

Figure 13. Figures of ACFs (right) and PACFs (left) for prescribing rate (Lag 1 differences).

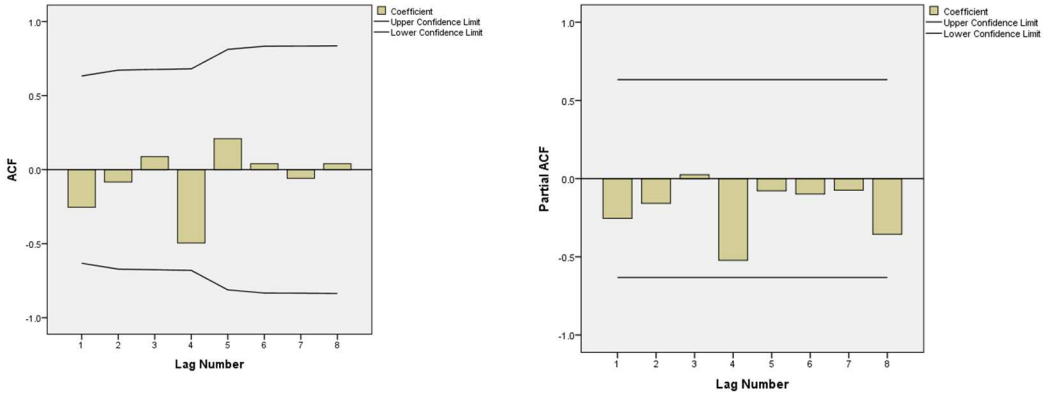

Figure 14. Figures of ACFs (right) and PACFs (left) for mortality of opioids (Lag 1 differences).

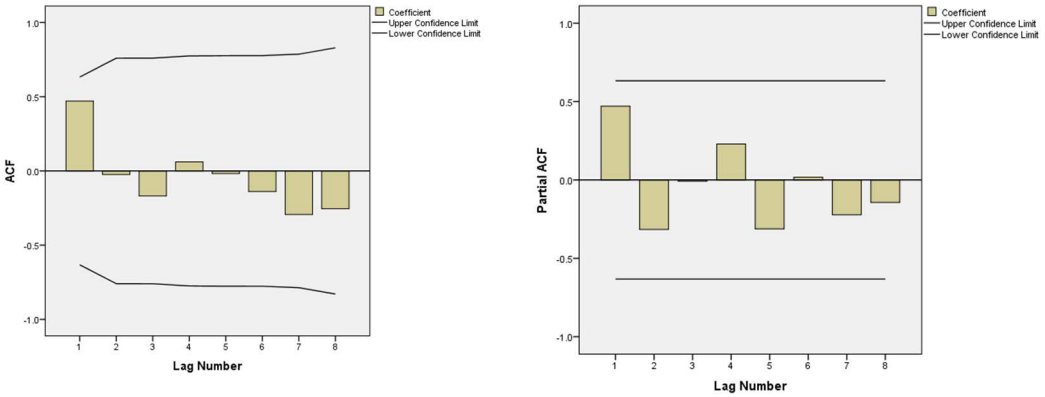

Figure 15. Figures of ACFs (right) and PACFs (left) for mortality of heroin and synthetic opioids (Lag 1 differences).

Analysis Results for Objective 1

ITS Analysis of Prescribing Rate

Table 6 shows the results of ITS analysis of prescribing rate. The $R^2 = 0.957$, indicating that approximately 95.7% of the total variation in the series could be explained by the model. The term for baseline trend (β_1) indicated that before the intervention, there was no significant year-to-year change in terms of the lag 1 differences of prescribing rate (Y_t-Y_{t-1}) ($p = 0.231$). The term for level change after intervention (β_2), indicated that immediately following the intervention, the lag 1 difference of prescribing rate (Y_t-Y_{t-1}) did not change significantly ($p = 0.127$). The term for trend changes after intervention (β_3) indicated that there was no significant year-to-year change in terms of the lag 1 differences of prescribing rate (Y_t-Y_{t-1}), comparing to trend before the intervention ($p = 0.102$).

The assumptions of the time-series analysis were examined (Figures 16-17 and Table 7). Normality of the residuals was checked using the Shapiro-Wilk normality test and the assumption was satisfied (W (10) = 0.982, p = 0.973). The assumption of homogeneity of variance and zero mean of residuals was checked using the plot of standardized residuals versus predicted values (see Figure 16) and was satisfied as the data points were randomly distributed around the 0-horizontal line. The assumption of independence of residuals was evaluated using ACFs and PACFs of the residuals (Table 7 and Figure 17) and was satisfied as 1) all results of the Ljung-Box Q tests were not significant ($p > 0.05$, Table 7), and 2) all ACFs and PACFs were within the 95% confidence bounds (Figure 17).

Table 6.

Results of ITS Analysis of Prescribing Rate

	Coefficient	*SE*	*t*	*p*
Intercept (β_0)	13.720	9.712	1.413	.207
Baseline trend (β_1)	-3.520	2.643	-1.332	.231
Level change after intervention (β_2)	-13.120	7.398	-1.774	.127
Trend change after intervention (β_3)	5.791	2.997	1.932	.102

Note: An ARIMA (0, 1, 0) model was employed. R^2 = 0.957. *SE* = standard error, $t = t$ statistic, $p = p$ value.

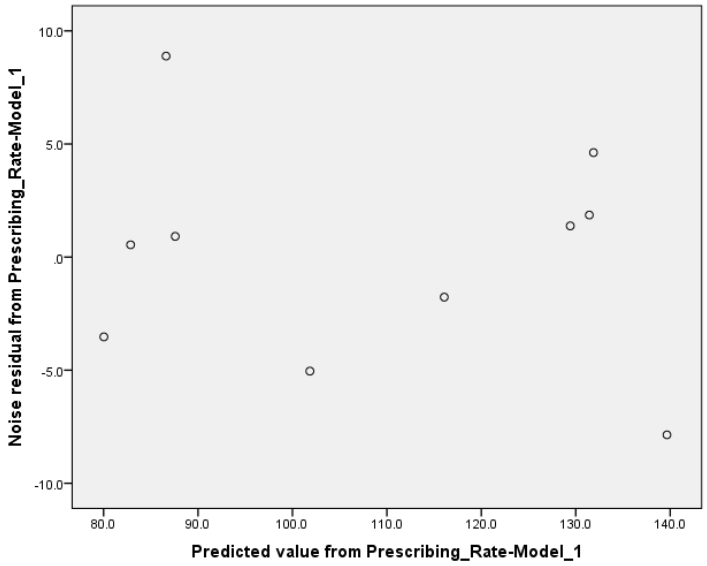

Figure 16. Plot of standardized residuals and predicted values.

Table 7.

ACFs and PACFs for the Residuals

			Box-Ljung statistic				
Lag	Autocorrelation	*SE*	Value	*df*	*p*	Partial autocorrelation	*SE*
1	-.382	.316	1.942	1	.163	-.382	.316
2	-.149	.359	2.275	2	.321	-.345	.316
3	-.060	.365	2.337	3	.506	-.356	.316
4	.315	.366	4.324	4	.364	.095	.316
5	-.403	.393	8.220	5	.145	-.383	.316
6	.143	.432	8.834	6	.183	-.168	.316
7	-.032	.437	8.874	7	.262	-.299	.316
8	.144	.437	10.123	8	.256	-.208	.316

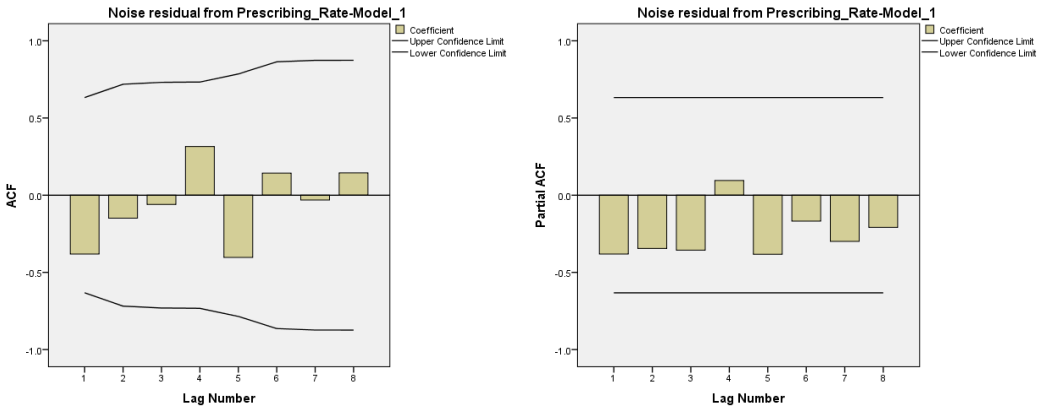

Figure 17. Figures of ACFs (right) and PACFs (left) for the residuals.

ITS Analysis of Mortality of Opioids

Table 8 shows the results of ITS analysis of mortality of opioids, with ARIMA (1,1,1) modeling. Appendix A shows the ARIMA models that were fit but deemed inappropriate due to violation of model assumptions. The $R^2 = 0.859$, indicating that approximately 85.9% of the total variation in the series could be explained by the model. The term for baseline trend (β_1) indicated that before the intervention, there was no significant year-to-year change in terms of the lag 1 difference of mortality of opioids (Y_t-Y_{t-1}) ($p = 0.277$). The term for level change after intervention (β_2), indicated that immediately following the intervention, the lag 1 difference of mortality of opioids (Y_t-Y_{t-1}) significantly dropped by 40.033 ($p = 0.043$). The term for trend change after intervention (β_3) indicated that there was no significant year-to-year change in terms of the lag 1 differences of mortality of opioids (Y_t-Y_{t-1}), comparing to trend before the intervention ($p = 0.960$).

The assumptions of the time-series analysis were examined (Figures 18-19 and Table 9). Normality of the residuals was checked using the Shapiro-Wilk normality test

and the assumption was satisfied (W (10) = 0.655, p = 0.078). The assumption of homogeneity of variance and zero mean of residuals was checked using the plot of standardized residuals versus predicted values (see Figure 18) and was satisfied as the data points were randomly distributed around the 0-horizontal line. The assumption of independence of residuals was evaluated using ACFs and PACFs of the residuals (see Table 9 and Figure 10) and was satisfied as 1) all results of the Ljung-Box Q tests were not significant ($p > 0.05$, Table 9), and 2) all ACFs and PACFs were within the 95% confidence bounds (see Figure 19).

Table 8.

Results of ITS Analysis of Mortality of Opioids

	Coefficient	*SE*	*t*	*p*
Intercept (β_0)	-8.619	16.811	-.513	.635
Baseline trend (β_1)	5.971	4.750	1.257	.277
Level change after intervention (β_2)	-40.033	13.676	-2.927	.043
Trend change after intervention (β_3)	.220	4.135	.053	.960

Note: An ARIMA(1, 1, 1) model was employed. R^2 = 0.859. *SE* = standard error, $t = t$ statistic, $p = p$ value.

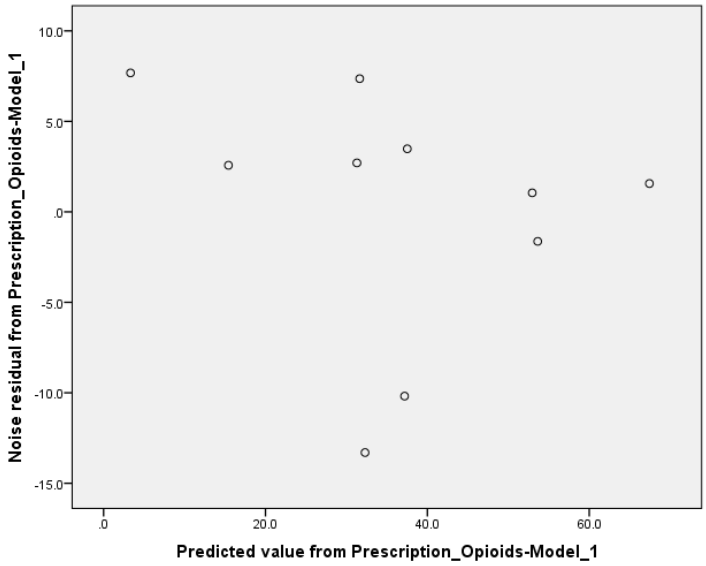

Figure 18. Plot of standardized residuals and predicted values.

Table 9.

ACFs and PACFs for the Residuals

			Box-Ljung statistic				
Lag	Autocorrelation	*SE*	Value	*df*	*p*	Partial autocorrelation	*SE*
1	-.122	.316	.200	1	.655	-.122	.316
2	-.389	.321	2.471	2	.291	-.410	.316
3	-.174	.365	2.992	3	.393	-.356	.316
4	-.095	.373	3.174	4	.529	-.528	.316
5	.420	.376	7.405	5	.192	-.044	.316
6	.034	.420	7.440	6	.282	-.254	.316
7	-.223	.420	9.425	7	.224	-.269	.316
8	.025	.432	9.461	8	.305	-.118	.316

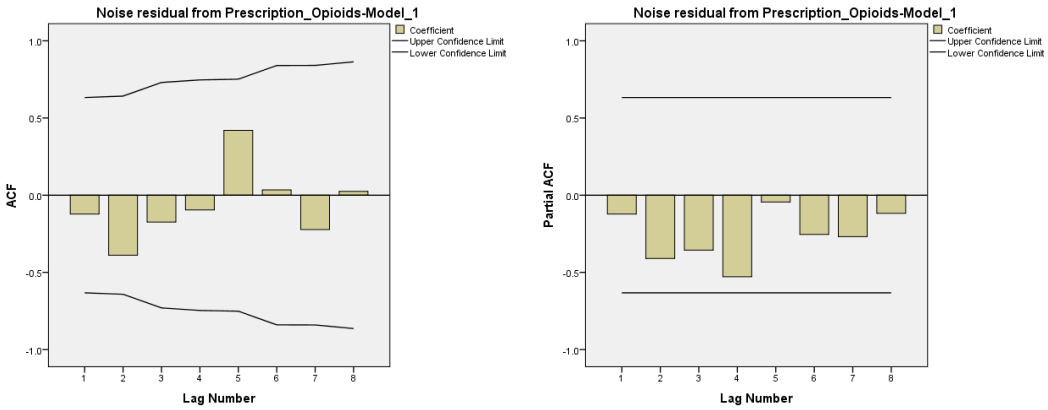

Figure 19. Figures of ACFs (right) and PACFs (left) for the residuals.

ITS Analysis of Mortality of Heroin and Synthetic Opioids

Table 10 shows the results of ITS analysis of mortality of heroin and synthetic opioids, with ARIMA (2,1,0) modeling. Appendix B shows the ARIMA models that were fit but deemed inappropriate due to violation of model assumptions. The $R^2 = 0.970$, indicating that approximately 97.0% of the total variation in the series could be explained by the model. The term for baseline trend (β_1) indicated that before the intervention, there was no significant year-to-year change in terms of the lag 1 difference of mortality of heroin and synthetic opioids (Y_t-Y_{t-1}) ($p = 0.139$). The term for level change after intervention (β_2), indicated that immediately following the intervention, the lag 1 difference of mortality of heroin and synthetic opioids (Y_t-Y_{t-1}) did not change significantly ($p = 0.372$). The term for trend changes after intervention (β_3) indicated that there was no significant year-to-year change in terms of the mortality of heroin and synthetic opioids (Y_t-Y_{t-1}), comparing to trend before the intervention ($p = 0.472$).

The assumptions of the time-series analysis were examined (see Figures 20-21 and Table 11). Normality of the residuals was checked using the Shapiro-Wilk normality test and the assumption was satisfied ($W(10) = 0.970$, $p = 0.890$). The assumption of homogeneity of variance and zero mean of residuals was checked using the plot of standardized residuals versus predicted values (Figure 20) and was satisfied as the data points were randomly distributed around the 0 horizontal line. The assumption of independence of residuals was evaluated using ACFs and PACFs of the residuals (see Table 11 and Figure 21) and was satisfied as 1) all results of the Ljung-Box Q tests were not significant ($p > 0.05$, Table 11), and 2) all ACFs and PACFs were within the 95% confidence bounds (see Figure 21).

Table 10.

Results of ITS Analysis of Mortality of Heroin and Synthetic Opioids

	Coefficient	*SE*	*t*	*p*
Intercept (β_0)	-30.924	39.598	-.781	.470
Baseline trend (β_1)	10.673	10.884	.981	.372
Level change after intervention (β_2)	-50.443	28.698	-1.758	.139
Trend change after intervention (β_3)	8.349	10.749	.777	.472

Note: An ARIMA(2, 1, 0) model was employed.)." = 0.970. *SE* = standard error, *t* = *t* statistic, *p* = *p* value.

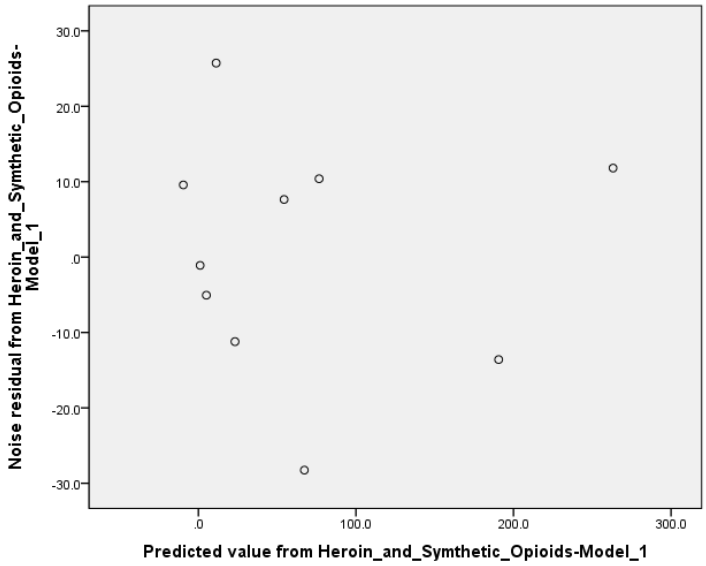

Figure 20. Plot of standardized residuals and predicted values.

Table 11.

ACFs and PACFs for the Residuals

			Box-Ljung statistic				
Lag	Autocorrelation	*SE*	Value	*df*	*p*	Partial autocorrelation	*SE*
1	-.384	.316	1.970	1	.160	-.384	.316
2	-.179	.360	2.453	2	.293	-.384	.316
3	-.011	.369	2.455	3	.483	-.350	.316
4	-.007	.369	2.456	4	.652	-.395	.316
5	.231	.369	3.735	5	.588	-.086	.316
6	-.150	.383	4.407	6	.622	-.161	.316
7	.022	.389	4.427	7	.730	-.013	.316
8	-.067	.389	4.694	8	.790	-.086	.316

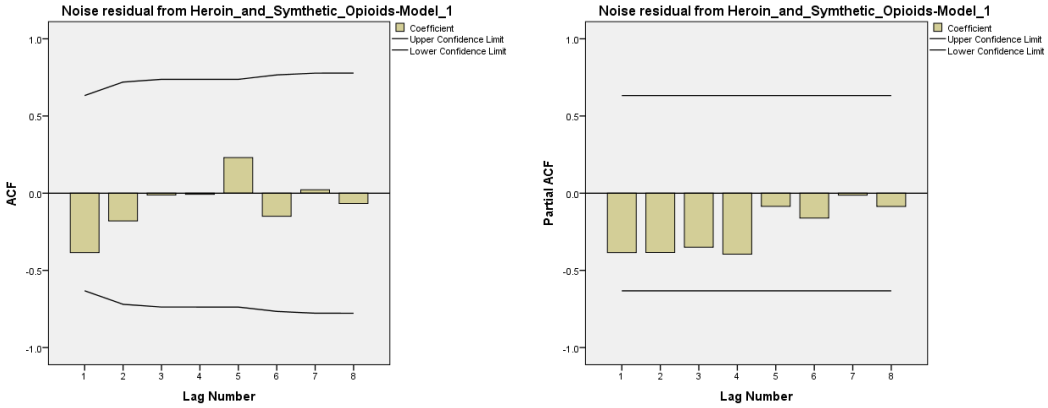

Figure 21. Figures of ACFs (right) and PACFs (left) for the residuals.

Analysis Results of Objective 2

Objective 2 was to determine the relationships between the two mortality measures (mortality of opioids and mortality of heroin and synthetic opioids) and prescribing rate. ARIMA(0, 0, 0) models with lag 1 differences of mortality of opioids and mortality of heroin and synthetic opioids as the dependent variables and lag 1 differences of prescribing rate as the independent variable were performed.

Figures 22 and 23 present the scatter plots of lag 1 differences of mortality of opioids and mortality of heroin and synthetic opioids, and lag 1 differences of prescribing rate. Table 12 presents the results of bivariate time-series analyses. It appeared that there was no statistically significant relationship between prescribing rate (in terms of lag 1 differences of prescribing rate) and mortality of opioids (in terms of lag 1 differences of mortality of opioids) ($t = 1.338$, $p = 0.218$). There was also no statistically significant relationship between prescribing rate (in terms of lag 1 differences of prescribing rate)

and mortality of heroin and synthetic opioids (in terms of lag 1 differences of mortality of heroin and synthetic opioids) (t = -0.982, p = 0.355).

The assumptions of the time-series analysis were examined (see Figures 24-27 and Tables 13-14). Normality of the residuals was checked using the Shapiro-Wilk normality test and the assumption was satisfied for both models ($W(10) = 0.900$, p = 0.220; $W(10) = 0.856$, $p = 0.068$). The assumption of homogeneity of variance and zero mean of residuals was checked using the plot of standardized residuals versus predicted values (see Figures 24-25) and was satisfied as the data points were randomly distributed around the 0 horizontal line. The assumption of independence of residuals was evaluated using ACFs and PACFs of the residuals (see Table 14 and Figures 26-27) and was satisfied as 1) all results of the Ljung-Box Q tests were not significant ($p > 0.05$, Table 14), and 2) all ACFs and PACFs were within the 95% confidence bounds (see Figures 26-27).

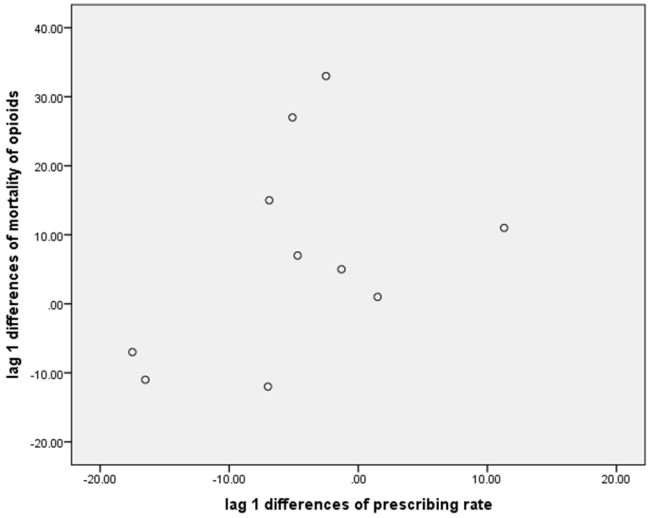

Figure 22. scatter plot of lag 1 differences of mortality of opioids and lag 1 differences of prescribing rate.

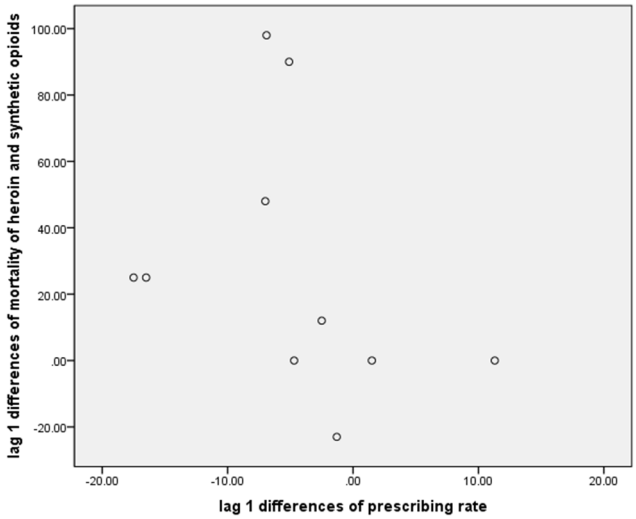

Figure 23. scatter plot of lag 1 differences of mortality of heroin and synthetic opioids and lag 1 differences of prescribing rate.

Table 12.

Results of Bivariate Analyses

DV		Coefficient	*SE*	*t*	*p*	R^2
Lag 1 differences of mortality of opioids	Intercept (β_0)	10.699	5.411	1.977	.083	0.183
	Slope (β_1)	.780	.583	1.338	.218	
Lag 1 differences of mortality of heroin and synthetic opioids	Intercept (β_0)	19.835	14.873	1.334	.219	0.108
	Slope (β_1)	-1.574	1.603	-.982	.355	-1.574

Note: Two ARIMA(0, 0, 0) models were employed. R^2 = 0.970. *SE* = standard error, *t* = *t* statistic, *p* = *p* value.

Table 13.

Results of Shapiro-Wilk Tests

DV	*W*	*df*	*p*
Lag 1 differences of mortality of opioids	.900	10	.220
Lag 1 differences of mortality of heroin and synthetic opioids	.856	10	.068

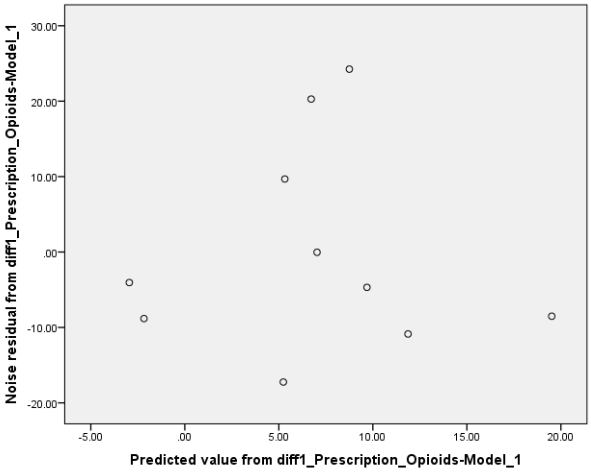

Figure 24. Plot of standardized residuals and predicted values (*DV* = Lag 1 differences of mortality of opioids).

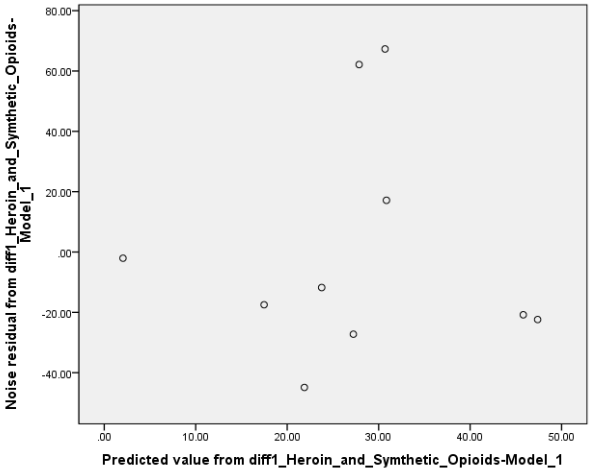

Figure 25. Plot of standardized residuals and predicted values (*DV* = Lag 1 differences of mortality of heroin and synthetic opioids).

Table 14.

ACFs and PACFs for the Residuals

				Box-Ljung statistic				
DV	Lag	Autocorrelation	*SE*	Value	*df*	*p*	Partial autocorrelation	*SE*
1	1	-.292	.316	1.133	1	.287	-.292	.316
	2	-.036	.342	1.153	2	.562	-.132	.316
	3	-.148	.342	1.528	3	.676	-.221	.316
	4	-.301	.349	3.334	4	.504	-.497	.316
	5	.370	.374	6.623	5	.250	.038	.316
	6	.032	.409	6.655	6	.354	.074	.316
	7	.024	.409	6.678	7	.463	-.028	.316
	8	-.102	.409	7.301	8	.505	-.129	.316
2	1	.540	.316	3.895	1	.058	.540	.316
	2	-.008	.398	3.896	2	.143	-.424	.316
	3	-.254	.398	5.002	3	.172	-.033	.316
	4	-.122	.414	5.300	4	.258	.146	.316
	5	-.091	.418	5.498	5	.358	-.289	.316
	6	-.176	.419	6.424	6	.377	-.099	.316
	7	-.226	.427	8.474	7	.293	-.037	.316
	8	-.153	.439	9.877	8	.274	-.120	.316

Note: DV 1 = Lag 1 differences of mortality of opioids, 2 = Lag 1 differences of mortality of heroin and synthetic opioids.

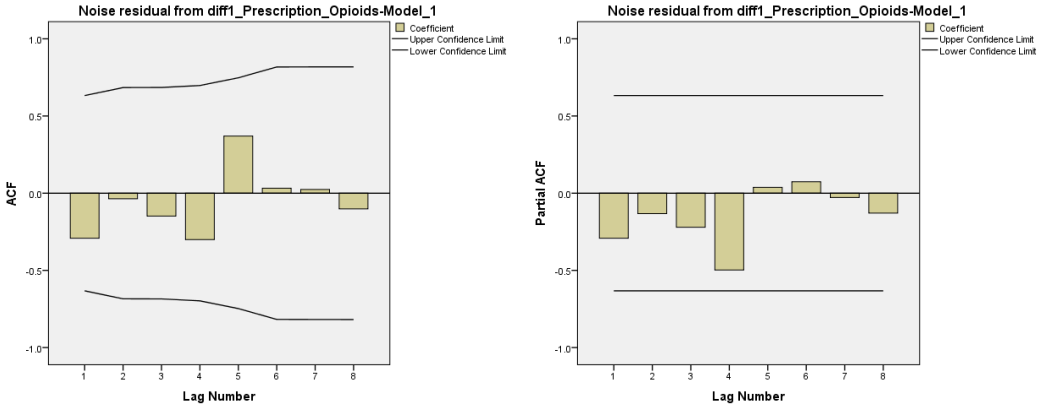

Figure 26. Figures of ACFs (right) and PACFs (left) for the residuals (DV = Lag 1 differences of mortality of opioids).

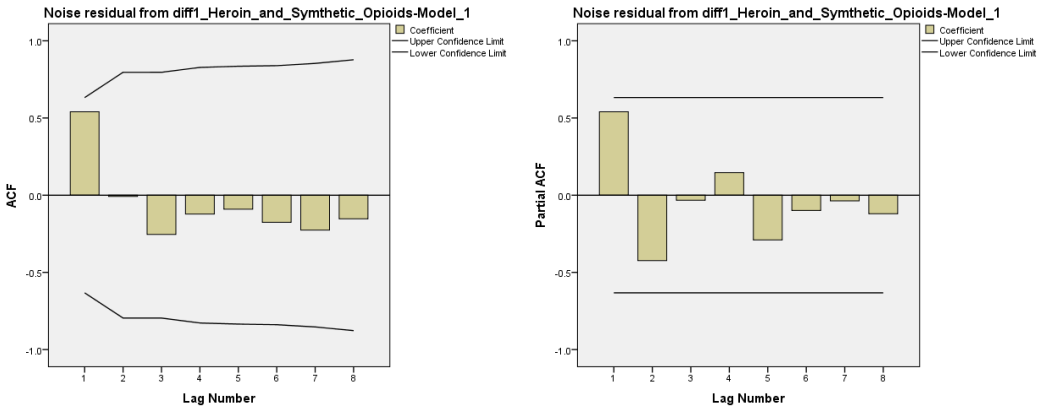

Figure 27. Figures of ACFs (right) and PACFs (left) for the residuals (*DV* = Lag 1 differences of mortality of heroin and synthetic opioids).

Summary

A brief summary of the findings for each research questions is outlined. Research questions 1a through 1c were answered with a simple review of the data for each category: prescribing rates, arrest rates for possession of heroin and synthetic opioids, and arrests rates for trafficking of heroin and synthetic opioids. Research questions 1d through 1g were answered through interrupted time series analyses.

According to the CDC (n.d.) prescribing rate maps, opioid prescribing rates in Jefferson County, Kentucky did decrease after the passage of Kentucky's HB1. The prescribing rate decreased from 130.8 prescriptions per 100 U.S. citizens in 2011 to 114.3 prescriptions per 100 U.S. citizens in 2012. Using these statistics, it is clear that some patients received multiple opioid prescriptions throughout each year. The prescribing rate in Jefferson County, KY continued to decrease after the passage of Kentucky's HB1 to 96.8 prescriptions per 100 U.S. citizens in 2013. The prescribing rates continued to decrease, although not as dramatically, from 2013 through 2017. In the context of this study, this decrease in prescriptions would indicate a decrease in the supply of prescription opioids. It should be noted that prescribing rates had begun a slight decrease prior to the passage of HB1.

As per LMPD (n.d.) arrest data, the arrest rates for possession of heroin and synthetic opioids did increase. The arrest rate climbed from 107 arrests in 2011 to 436 arrests in 2012. The arrest rate continued to climb after the passage of Kentucky's HB1 in 2012 to 792 arrests in 2013. The arrest rate continued to climb, peaking in 2016 at 1381 arrests for possession of heroin and synthetic opioids. The arrest rate dropped in 2017 to 1237 arrests. In the context of this study, the increase in arrest rates seems to indicate an increase in demand for heroin and synthetic opioids after the passage of Kentucky's HB1 in 2012. It could be argued that the increase in arrests could is the result of aggressive law enforcement actions. The simultaneous decrease in opioid prescriptions, resulting in fewer opioids available for diversion, considered along with the simultaneous increase in arrests for trafficking in heroin and synthetic opioids, leads this researcher to believe that

demand for heroin and synthetic opioids increased. Put another way, as there were fewer prescription opioids available to dealers and addicts, addicts began to demand more heroin and synthetic opioids. Using the statistics for arrests for trafficking in heroin and synthetic opioids, it seems apparent that drug dealers were ready to meet the supply for this new demand. It should be noted that arrest rates for possession of heroin and synthetic opioids had begun to climb prior to the passage of HB1.

As per LMPD (n.d.) arrest data, the arrest rates for trafficking of heroin and synthetic opioids did increase. Arrest rates increased from 46 arrests in 2011 to 147 arrests in 2012. Arrest rates continued to increase with 280 arrests in 2013. In the context of this study, the increase in arrests for trafficking in heroin and synthetic opioids indicates an increase in supply of heroin and synthetic opioids. Again, it could be argued that the increase in arrests could is the result of aggressive law enforcement actions. The simultaneous decrease in opioid prescriptions, resulting in fewer opioids available for diversion, considered along with the simultaneous increase in arrests for possession of heroin and synthetic opioids, leads this researcher to believe that supply of heroin and synthetic opioids increased. Put another way, this researcher believes that as there were fewer prescription opioids available to dealers, defined by the decrease in opioid prescriptions, dealers increased their supply of heroin and synthetic opioids to meet the demands of local opioid addicts. It should be noted that arrest rates for trafficking of heroin and synthetic opioids had begun to increase prior to the passage of HB1.

An ARIMA model (0, 1, 0) was employed and it was determined that there were no significant changes in prescribing rates after the implementation of HB1. 95.7% of the

data variation can be explained by the model. This finding indicates that the implementation of HB1 had no significant effect prescribing rates in Jefferson County, KY.

An ARIMA model (1, 1, 1) was employed and it was determined that there was a significant decrease in prescription opioid overdose fatality rates immediately after the implementation of HB1. 85.9% of the data variation can be explained by the model. This finding indicates that the implementation of HB1 had an immediate effect, decreasing the prescription opioid overdose rate in Jefferson County, KY.

An ARIMA model (2, 1, 0) was employed and it was determined that there was no significant change in heroin and synthetic opioid overdose fatality rates after the implementation of HB1. 97.0% of the data variation can be explained by the model. This finding indicates that HB1 had no effect on the overdose fatality rates for heroin and synthetic opioids.

An ARIMA model (0, 0, 0) was employed and it was determined that there was no significant relationship between prescribing rates and heroin and synthetic opioid overdose fatality rates in this study. In the following chapter, I provide the interpretation, recommendations, and implications of the current study.

Chapter 5: Interpretation, Recommendations, and Implications

Introduction

The research questions were designed to inquire about the state of supply and demand for prescription opioids and heroin and synthetic opioids in Jefferson County, Kentucky after the implementation of Kentucky's HB1. The supply of prescription opioids was studied using data from the CDC's (n.d.) prescribing rate maps and LMPD's arrest records for trafficking of opioids. The demand for prescription opioids and heroin and synthetic opioids was studied using LMPD's (n.d.) arrest records for possession of opioids and heroin and synthetic opioids. Precisely, this study was concerned with the goal of determining whether or not the implementation of Kentucky's HB1 created an environment in which prescription opioid misusers made a rational choice to switch to heroin and synthetic opioid use. Such a switch to an unregulated, and more dangerous, illicit market drug would be expected to result in significant increases in opioid overdose fatalities overall. Thus, the ultimate goal of this study was to discover and quantify any relationships between the implementation of Kentucky's HB1 and the documented increase in heroin and synthetic opioid overdose rates.

Key Findings

There were multiple key findings for this study. Research question 1a asked if prescribing rates decreased after the implementation of Kentucky's HB1. This question was designed to be a measure of the supply of prescription opioids both before and after the implementation of Kentucky's HB1. As can be seen in Figure 1, prescribing rates had begun to moderately decrease prior to the implementation of HB1 in 2012. However, a

dramatic decrease in prescribing rates was seen in 2012, the year in which Kentucky's HB1 was implemented, and the decrease continued through 2017. Prescribing rates decreased after the implementation of HB1. A decrease in prescription opioid rates was interpreted to mean that the supply of prescription opioids had decreased and that, as a consequence, there would have been fewer prescription opioids available for diversion to the illicit opioid market.

Research question 1b asked whether arrest rates for possession of heroin and synthetic opioids increased after the implementation of Kentucky's HB1. Given the decrease in opioid prescription rates, it was theorized that the demand for heroin and synthetic opioids would increase because they would be used as replacement opioids. As can be seen in Figure 2, arrest rates for heroin and synthetic opioids increased moderately between 2007 and 2011. Arrest rates for possession of heroin and synthetic opioids dramatically increased in 2012 and continued to increase through 2016. Arrests rates for possession of heroin and synthetic opioids increased after the implementation of Kentucky's HB1 in 2012. An increase in arrest rates for possession of heroin and synthetic opioids was interpreted as an increase in the demand for the illicitly manufactured drugs.

Research question 1c asked whether trafficking of heroin and synthetic opioids increased after the implementation of Kentucky's HB1. Arrest rates for trafficking of heroin and synthetic opioids had moderately increased from 2007 through 2011. As can be seen in Figure 3, arrest rates increased dramatically in 2012 and continued to climb through 2016. Arrest rates for trafficking of heroin and synthetic opioids increased after

the implementation of HB1. An increase in arrest rates for trafficking of heroin and synthetic opioids was interpreted as an increase in supply of heroin and synthetic opioids.

Research questions 1a through 1c were intended to explore the aspects of supply and demand. The answers to research questions 1a through 1c indicate that there was a decrease in the supply of prescription opioids and a simultaneous increase in both supply and demand for heroin and synthetic opioids. These findings were consistent with the hypothesis that the implementation of HB1 could have created a supply and demand environment in which prescription opioid addicts might have made a rational choice to switch to heroin and synthetic opioid use.

Research question 1d asked if there is a statistically significant difference in the prescription opioid overdose fatality rate after the implementation of HB1. As can be seen in Table 1, the opioid prescribing rate in Jefferson County, Kentucky remained somewhat stable between 2007 and 2011. Then in 2012, the year that HB1 was implemented, the prescribing rate began a continuous decrease through 2017. An interrupted time series study was conducted to determine the significance of the decrease. Interrupted time series analysis indicated that the trajectory of opioid prescribing rates did not significantly change as a direct result of the implementation of Kentucky's HB1. Although prescribing rates did decrease, consistent with the goal of HB1, the decrease was not a direct result of the implementation of HB1. This finding also indicates any decrease in the supply of prescription opioids was not a direct result of the implementation of HB1.

Research question 1e asked if there is a statistically significant difference in the prescription opioid overdose fatality rate after the implementation of Kentucky's HB1. As can be seen in Table 1, the mortality rate or prescription opioids trended downward for the first four years after the implementation of Kentucky's HB1. After the initial downward trend, however, mortality rates began to climb again in 2016. An interrupted time series study was conducted to determine any significance of the relationship between HB1 and the decrease in prescription opioid overdose fatality incidents. An interrupted time series analysis indicated that the relationship between the downward trajectory of prescription opioid overdose fatalities and the implementation of Kentucky's HB1 was significantly significant. This finding is consistent with the goals of HB1.

Research question 1f asked if there is a statistically significant difference in the heroin and synthetic opioid overdose rate after the implementation of Kentucky's HB1. As can be seen in Table 1, the mortality rate for heroin and synthetic opioid overdose was zero for the years of 2007 through 2010. In 2011, heroin and synthetic opioid overdose became an issue in Jefferson County, Kentucky. Beginning with 12 overdose fatalities in 2011, the heroin and synthetic opioid overdose fatality rate continuously climbed each year to 275 overdose fatalities in 2017. An interrupted time series study was conducted to determine the significance of the increase to the implementation of Kentucky's HB1. Although overdose fatality rates for heroin and synthetic opioids did increase after the implementation of HB1, interrupted time series analysis indicated that the increase was not significantly related to the implementation of Kentucky's HB1.

Finally, research question 1g asked if there is a statistically significant relationship between prescribing rates and heroin and synthetic opioid overdose fatality rates. It can be seen in Table 1 that there was a decrease in opioid prescribing rates and a simultaneous increase in heroin and synthetic opioid overdose rates. An interrupted time series study was conducted to determine the significance of a possible relationship. Interrupted time series analysis indicated that the decrease in opioid prescribing rates was not significantly related to either the decrease in prescription opioid overdose fatality rates or the increase in heroin and synthetic opioid overdose fatality rates after the implementation of Kentucky's HB1. This finding is inconsistent with the overall hypothesis that the implementation of HB1 had a causal effect on the increase in heroin and synthetic opioid overdose fatalities.

Interpretation of the Findings

Public policy is expected to have consequences. The intended consequence of HB1 was that there would be a decrease in opioid prescriptions resulting in fewer prescription drugs available for diversion to the illicit market (Kentucky General Assembly, 2012). This intended consequence was expected lead to a reduction in overdose incidents. HB1 was intended to address all prescription drug overdose incidents. Opioids are a special class of prescription drugs in that there are illicit options to fulfill an addict's needs. Heroin and illicitly produced synthetic opioids have traditionally filled the needs of addicts who cannot obtain regulated prescription opioids (Alpert et al., 2017; Cicero et al., 2014; Mars et al., 2014).

Unintended consequences of public policy are not always easy to predict. A study by Alpert et al., (2017) found that oxycontin addicts switched to heroin use as a result of a change in the oxycontin formula that made the drug more difficult to crush and use illicitly. I was concerned with the same type of unintended consequence as a result of the implementation of Kentucky's HB1. Specifically, I was concerned with identifying and quantifying any possible relationships between the implementation of Kentucky's HB1 and the documented increase in heroin and synthetic opioid overdose rates.

A reduction in prescriptions for opioids would mean that there were fewer prescription opioids available for diversion to the illicit market. Heroin and synthetic opioids can be manufactured in clandestine labs, thus bypassing the need for a doctor's prescription. These illicitly produced opioids can be marketed and used outside of the reach of public policies concerning PDMPs. It was hypothesized in this study that if HB1 resulted in fewer opioid prescriptions, opioid addicts were forced to make a rational choice: stop using opioids or seek out illicit alternatives. The hypothesis was not reinforced by this study.

Although the supply of prescription opioids did decrease while the demand for heroin and synthetic opioids increased, it does not appear that these findings were consistent with any relationship to the implementation of HB1. The findings of research questions 1a through 1c seem to indicate an environment in which a switch was made from prescription opioid abuse to heroin and synthetic opioid use. However, further findings for questions 1d, 1f, and 1g indicate that the environment was not induced by the implementation of HB1. Kentucky's HB1 does not seem to have created an environment

in which opioid addicts were forced to make a rational choice to switch to heroin and synthetic opioid use. Neither the reduction of opioid prescriptions nor the increase in heroin and synthetic opioid overdose fatalities was found to be significantly related to the implementation of HB1.

The only significant relationship found in this study was between the implementation of HB1 and the decrease in prescription opioid overdose fatalities. This finding indicates that HB1 ultimately acted exactly as intended. The overall opioid fatality rates increased dramatically when after the implementation of HB1 when prescription opioids, heroin, and synthetic opioids are considered. However, HB1 was not intended to affect heroin and synthetic opioid overdose fatality rates, only prescription opioid overdose fatality rates. Since the overall goal of HB1 was to decrease the rate of prescription opioid overdose fatalities, HB1 could be considered a successful policy implementation. This study hypothesized that although the prescription opioid overdose fatality rate deceased, the overall opioid rate increased as a result of the implementation of Kentucky's HB1. Had this been the case, HB1 would have ultimately been considered a failure for creating an environment in which more people ultimately died of opioid overdose. The results of this study do not find that this is the case. There was no relationship found between the implementation of HB1 and the rate of heroin and synthetic opioid overdose rates. Again, Kentucky's HB1 should be considered a successful policy implementation.

Limitations

The major limitation for quasi-experimental designs is that there is no control group by which to compare actual results. The assumptions for interrupted time series studies are normality of the residuals, homogeneity of variance and zero mean of residuals, and independence of residuals. Results of this study rely on these assumptions.

Further limitations include a human error and a lack of complete data for LMPD arrest records. All computer databases are susceptible to human error. Arresting officers input data concerning arrest charges. It would stand to reason that there might be some individual practices for inputting data and that this individualism might lead to inconsistencies. For example, some data in the LMPD arrest records includes arrests for generic controlled substance statutes that do not identify the drug seized. LMPD records include generic charges for possession of a controlled substance and trafficking of a controlled substance. It could be inferred that some of these arrests include arrests for opioids. However, none of these statistics could be used in this study due to a lack of identification of drug type possessed or trafficked by the arrestee.

Recommendations

Future Policy Indications

This study adds to the body of knowledge proclaiming success for PDMPs (CDC, 2017; Finklea et al., 2014; Gau & Brooke, 2017; Kentucky General Assembly, 2012). In addition to previous academic and organizational claims of success for PDMPs, future policymakers should add the current findings to research encouraging the implementation of PDMPs. If future research can determine the reason(s) behind increases in heroin and

synthetic opioid overdose rates, likely cost and purity of the drugs, then policy considerations should be made to combat the supply of these drugs (Alpert et al., 2017; Cicero et al., 2014).

Future Research

Research by Alpert et al. (2017) and Cicero et al. (2014) indicate that drug price, purity, and availability drive opioid addicts to make the switch to heroin and synthetic opioids use. A review of the data from this study clearly shows a dramatic increase in heroin and synthetic opioid overdose fatalities beginning near the implementation of HB1. Although this study clearly absolves HB1 of any culpability for the increase, something changed around the same time period to drive this shift in opioid abuse. Future research could attempt to identify other sources for encouraging this change.

Naloxone has become more available within the last decade. Future research testing relationships between naloxone and overdose rates could lead to a better understanding of the drug meant to reverse opioid overdose incidents. During my research for this study, I spoke to an emergency room nurse who explained that some opioid overdose fatality incidents occurred after having been previously revived with naloxone. She explained that when revived, the addict no longer feels the intoxicating effects of the opioid, so they add more of the drug into their bodies. This addition can lead to a second overdose and eventual fatality. Future research in this area could be lifesaving.

Implications

The current study has positive social implications at the individual, family, and societal levels. First, individuals who are addicted to prescription opioids need access to safer options. It appears that addicts have, for whatever reason, made a switch from prescription opioids to the unregulated and more dangerous illicit opioids, heroin and synthetic opioids. Foreseeing this need for options could lead to better policies with stronger incentives to seek addiction treatment rather than continue down the path of addiction.

In 2017, drug overdoses took more than 70,000 lives. 68% of those deaths were opioid related (CDC, n.d.). This statistic has overwhelming implications at the family and societal levels. Each opioid overdose death has implications at the family level because each victim has family members who are affected by the epidemic. Each victim is potentially leaving a mother, father, child, or many other family members to deal with the emotional toll of their death.

It has been estimated that the opioid epidemic has cost the United States more than one trillion dollars between the years 2001 and 2017 (Litton, 2018). This number implies enormous societal implications for positive social change. The estimation clearly indicates that the cost of the opioid epidemic is expensive to say the least. If an appropriate portion of this expense could be directed toward encouraging opioid addicts to receive treatment, rather than switch to heroin and synthetic opioids, we might see a decline in overdose deaths. The overall implications for positive social change could be measured in lives saved.

Conclusion

This study was conducted to identify and quantify possible relationships between the implementation of Kentucky's HB1 and opioid overdose fatality rates. Kentucky's HB1 was intended to influence prescribing rates for all prescription drugs. After the implementation of HB1, heroin and fentanyl overtook prescription opioids as the number one drug identified in medical examiners' overdose toxicology reports (Office of the State Medical Examiner, n.d.). After HB1 was implemented, the supply and demand for heroin and synthetic opioids appear to have increased. This was determined by studying the arrest rates for trafficking and possession of heroin and synthetic opioids.

This study determined that HB1 ultimately acted as intended. Although the prescribing rate in Jefferson County, Kentucky declined, the decrease was not found to be directly related to the implementation Of HB1. However, the secondary, and most important, intention of HB1 was realized. The decrease in prescription opioid overdose fatalities was found to be directly related to the implementation of HB1.

To incite true positive social change, it must be recognized when public policy encourages positive social results. HB1 appears to have been validated by this study. The bill achieved the goal of saving lives. In addition to this recognition, however, it must be admitted that there was still a dramatic increase in heroin and synthetic opioid overdose rates in the past decade. Something encouraged this change. Researchers must not only continue to search for the sources of the change, but also effective responses to the change. It could be argued that finding the root cause of opioid abuse in specific populations would point us in the right direction for finding solutions. 68% of more than

70,000 drug overdose fatalities in 2017 were opioid related (CDC, n.d.). This statistic demands further research and understanding of the opioid epidemic.

References

Alpert, A., Powell, D., & Licardo Pacula, R. (2017, January). Supply-side drug policy in the presence of substitutes: Evidence from the introduction of abuse-deterrent opioids. Retrieved from http://www.nber.org/papers/w23031

Aronson, S. M. (2011). From mindless medication to reckless recreation. *Medicine & Health Rhode Island, 94*(8), 223. Retrieved from https://ezp.waldenulibrary.org/login?url=https://search.ebscohost.com/login.aspx?direct=true&db=a9h&AN=64731713&site=eds-live&scope=site

Atkinson, T., Schatman, M., Fudin, J. (2014). The damage done by the war on opioids: The pendulum has swung too far. *Journal of Pain Research, 7*, 265-268. doi10.2147/JPR.S65581

Beccaria, C. (1778). Dei Delitti e Delle Pene. Philadelphia: Bell, R. Retrieved from http://www.constitution.org/cb/crim_pun.txt

Bhalla, I., Cohen, N., Hupt, C., Stith, K., & Zhong, R. (2018). The role of civil commitment in the opioid crisis. *The Journal of Law, Medicine, & Ethics, 46*, 343-350. doi: 10.1177/1073110518782943

Beletski, L. (2018). Deploying prescription drug monitoring to address the overdose crisis: Ideology meets reality. *Indiana Health Law Review, 15*(2), 139-187. Northeastern University School of Law Research Paper No. 323-2018

Centers for Disease Control and Prevention. (n.d.). A public health crisis. Retrieved from https://www.cdc.gov/opioids/strategy.html

Centers for Disease Control and Prevention. (n.d.). CDC Wonder. Retrieved from https://wonder.cdc.gov/

Centers for Disease Control and Prevention. (n.d). Opioid overdose. Retrieved from https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html

Centers for Disease Control and Prevention. (2017). What states need to know about PDMPs. Retrieved from https://www.cdc.gov/drugoverdose/pdmp/states.html

Cicero, T., Ellis, M., Surratt, H., & Kurtz, S. (2014). The changing face of heroin use in the United States: A retrospective analysis of the past 50 years. *JAMA Psychiatry, 71*(7), 821-826. doi:10.1001/jamapsychiatry.2014.366

Compton W., Jones, C., & Baldwin, G. (2016). Relationship between nonmedical prescription-opioid use and heroin use. *The New England Journal of Medicine, 374*(2), 154-163. doi:10.1056/NEJMra1508490

Cornish, D. B., & Clarke, R. V. G. (1986). The reasoning criminal: Rational choice perspectives on offending. New York: Springer-Verlag.

Dennenberg, R. & Curtiss, C. (2016). Appropriate use of opioids in managing pain: A review of best practices for alleviating suffering, while avoiding risks. *American Journal of Nursing, 116*(7), 26-38. doi: 10.1097/01.NAJ.0000484931.50778.6f. CE

Drug Enforcement Administration. (2017). National drug threat assessment. Retrieved from https://www.dea.gov/sites/default/files/2018-07/DIR-040-17_2017-NDTA.pdf

Drug Enforcement Administration. (n.d.). Drug scheduling. Retrieved from https://www.dea.gov/drug-scheduling

Drug Enforcement Administration. (n.d.). Narcotics (opioids). Retrieved from https://www.dea.gov/taxonomy/term/331

Dubois, J., Chibnall, J., Anderson, E., Eggers, M., Baldwin, K., & Vasher, M. (2016). A mixed-method analysis of reports on 100 cases of Improper prescribing of controlled substances. *Journal of Drug Issues, 46*(4), 457-472. doi: 10.1177/0022042616661836

Felter, C. (2017). "The US opioid epidemic," Council on Foreign Relations. Retrieved from www.cfr.org/backgrounder/us-opioid-epidemic

Fink, D., Schleimer, J., Sarvet, A., Grover, K. Delcher, C., Castillo-Carniglia, A., Kim, J, Rivera-Aguirre, A., Henry, S., Martins, S., Cerda, M. (2018). Association between prescription drug monitoring programs and nonfatal and fatal drug overdoses: A systematic review. *Annals of Internal Medicine, 168*(11), 783–790. doi:10.7326/M17-3074

Finklea, K., Bagalman, E., & Sacco, L. (2014). *Prescription drug monitoring programs*. Retrieved from https://www.everycrsreport.com/files/20140324_R42593_b5e6bc388e7be92c9a1be399db0878fa177c6941.pdf

Fresher, S. (2018). Opioid addiction litigation and the wrongful conduct rule. *University of Colorado Law Review, 89*(4), 1311-1340. Retrieved from http://lawreview.colorado.edu/wp-content/uploads/2018/07/89.4-Fresher.pdf

Fudin, J. (2015). The economics of opioids: Abuse, REMS, and treatment benefits. *American Journal of Managed Care, 21*, S188a-S194a. Retrieved from https://www.ajmc.com/journals/supplement/2015/ace0029_aug15_painrems/ace0029_aug15_painrems_fudin

Fujii, M., Hodges, A., Russell, R., Roensch, K., Beynnon, B., Ahern, T., Holoch, P., Moore, J., Ames, S.E., & Maclean, C. (2018). Post-discharge opioid prescribing and use after common surgical procedure. *Journal of the American College of Surgeons, 226*(6), 1004-1012. doi: 10.1016/j.jamcollsurg.2018.01.058

Gau, J., Brooke, E. (2017). An assessment of the impact of a multipronged approach to reducing problematic pain clinics in Florida. *Journal of Drug Issues, 47*(4), 185-204.

Gibson, G. (2018). Voters in opioid-plagued districts demand solutions from candidates. Retrieved from https://www.reuters.com/article/us-usa-election-opioids/voters-in-opioid-plagued-districts-demand-solutions-from-candidates-idUSKCN1J11BE

Guevremont, N., Barnes, M., Haupt, C. (2018). Physician autonomy and the opioid crisis. *The Journal of Law, Medicine and Ethics, 46*, 203-219. doi: 1073110518782922

Guy, A. (2018). A surging drug epidemic: Time for Congress to enact a mandate on insurance companies and rehabilitation facilities for opioid and opiate addiction. *Cleveland-Marshall Journal of Law and Science, 31*(1), 5-28. Retrieved from https://engagedscholarship.csuohio.edu/cgi/viewcontent.cgi?article=1532&context=jlh

Hall, A., Logan, J., Toblin, R., Kaplan, J., Kraner, J., Bixler, D., Crosby, A., & Paulozzi, L. (2008). Patterns of abuse among unintentional pharmaceutical overdose fatalities. *Journal of the American Medical Association, 300*(22), 2613-2620. doi:10.1001/jama.2008.802

Harocopos, A. & Bennett, A. (2015). Routes into opioid analgesic misuse: Emergent typologies of initiation. *Journal of Drug Issues, 45*(4), 385-395. doi: 10.1177/0022042615604345

Hollingsworth, A. Ruhm, C., & Simon, K. (2017) Macroeconomic conditions and opioid abuse. *Journal of Health Economics, 56*, 222-233. doi: 10.1016/j.jhealeco.2017.07.009

Hsien-Chang, L., Wang, Z., Boyd, C., Simoni-Wastila, L., & Buu, A. (2018). Associations between statewide prescription drug monitoring program (PDMP) requirement and physician patterns of prescribing opioid analgesics. *Addictive Behaviors, 76*, 348-354. doi: 10.1016/j.addbeh.2017.08.032

Hsu, D., McCarthy, J, & Stephens, K. (2017). Hospitalizations, costs, and outcomes associated with heroin and prescription opioid overdoses in the United States 2001- 12. *Addiction, 112*, 1558-1564. doi: 10.1111/add.13795.

IBM Corp. (2015). *IBM SPSS Forecasting 23*. Armonk, NY: IBM Corp.

Jackson, D. & Fritze, J. (2018). President Trump tries to project image of bipartisan action with opioid bill signing. Retrieved from https://www.usatoday.com/story/news/politics/2018/10/24/donald-trump-opioids-bill-signed-into-law-weeks-midterm-election/1750400002/

Jefferson County Coroner's Office. (2018). OD Running Count. Jefferson County Coroner's Office.

Kentucky General Assembly. (2012). HB1 18RS www version. Retrieved from http://www.lrc.ky.gov/record/18RS/hb1.htm

Lewy, J. (2013). The Army disease: Drug addiction and the Civil War. *War in History, 21*(1), 102-119. doi: 10.1177/0968344513504724

Li, G., Brady, J., Lang, B., Giglio, J., Wunsch, H., & DiMaggio, C. (2014). Prescription drug monitoring and drug overdose mortality. *Injury Epidemiology, 1*(9), doi: 10.1186/2197-1714-1-9

Lipman, A. (2015). Opioid abuse, politicians, and blame. *Journal of Positive Pain and Palliative Care Pharmocotherapy, 29*, 2-3. doi: 10.3109/15360288.2014.1004012

Litton, S. (2018). Economic toll of opioid crisis in U.S. exceeded $1 trillion since 2001. Altarum, Retrieved from https://altarum.org/news/economic-toll-opioid-crisis-us-exceeded-1-trillion-2001

Louisville Metro Police Department (n.d.) Crime reports. Retrieved from https://data.louisvilleky.gov/dataset/crime-reports

Lyapustina, T., Castillo, R., Omaki, E., Sheilds, W., McDonald, E., Rothman, R., & Gielen, A. (2017). The contribution of the emergency department to opioid pain reliever misuse and diversion: A critical review. *Pain Practice 17*(8), 1097-1104. doi: 10.1111/papr.12568

Mars, S., Bourgois, P., Karandinos, G., Montero, F., & Ciccarone, D. (2014). "Every 'never' I ever said came true": Transitions from opioid pills to heroin injecting. *International Journal of Drug Policy, 25*, 257-266. doi: 10.1016/j.drugpo.2013.10.004

McCabe, S., West, B., & Boyd, C. (2013). Leftover prescription opioids and nonmedical use among high school seniors: A multi-cohort national study. *Journal of Adolescent Health, 52*, 480-485. doi: 10.1016/j.jadohealth.2012.08.007

McLean, K. (2017). From "junkies" to "soccer moms": Newspaper representations of overdose, 1988-2014. *Critical Criminology, 25*, 411-432. doi: 10.1007/s10612-017-9350-2

McCoy, M, & Kanter, G. (2018). Campaign contributions from political action committees to members of Congressional committees responding to the opioid crisis, *Journal of the American Medical Association, 320*(14), 1489. doi: 10.1001/jama.2018.11338

McDonald, E., Kennedy-Hendricks, A., McGinty, E., Shields, W., Barry, C., & Gielen, A. (2017). Safe storage of opioid pain relievers among adults living in households with children. *Pediatrics, 139*(3), 1-8. doi: 10.1542/peds.2016-2161

McDonough, J. (2016). Behind the bipartisan kumbaya on opioids and drug abuse. *The Milbank Quarterly, 94*(2), 242-245. doi: 10.1111/1468-0009.12187

Meyer, R., Patel, A., Rattana, S., Quock, T., & Mody, S. (2014). Prescription opioid abuse: A literature review of the clinical and economic burden in the United States. *Population Health Management, 17*(6), 372-387. doi: 10.1089/pop.2013.0098

Moyo, P., Simoni-Wastila, Linda, Griffen, B., Onukwugha, E., Harrington, D., Alexander, G., & Palumbo, F. (2017). Impact of prescription drug monitoring programs (PDMPs) on opioid utilization among Medicare beneficiaries in 10 US states. *Addiction, 112*, 1784-1796. doi: 10.1111/add.13860

Muhuri, P., Gfroerer, J., & Davis, C. (2013). Associations of nonmedical pain reliever use and initiation of heroin use in the United States. Retrieved from https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm

Nam, Y., Shea, D., Shi, Y, & Moran, J. (2017). State prescription drug monitoring programs and fatal drug overdoses, *The American Journal of Managed Care, 23*(5), 297-303. doi: 10.1186/2197-1714-1-9

National Institute on Drug Abuse. (n.d.). FAQs about opioids. Retrieved from https://www.drugabuse.gov/publications/opioid-facts-teens/faqs-about-opioids

National Institute on Drug Abuse. (2016). Fentanyl. Retrieved from https://www.drugabuse.gov/publications/drugfacts/fentanyl

National Institute on Drug Abuse. (2018). Prescription opioids. Retrieved from https://www.drugabuse.gov/publications/drugfacts/prescription-opioids.

National Institute on Drug Abuse. (n.d.). What is fentanyl. Retrieved from https://www.drugabuse.gov/publications/drugfacts/fentanyl

National Institute on Drug Abuse. (n.d.). What is heroin? Retrieved from https://www.drugabuse.gov/publications/drugfacts/heroin.

National Institute on Drug Abuse. (2018). Kentucky opioid summary. Retrieved from https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/kentucky-opioid-summary.

Office of the State Medical Examiner. (n.d.). Office of the State Medical Examiner. Retrieved from https://justice.ky.gov/Pages/Kentucky-Medical-Examiners-Office.aspx

Office of the State Medical Examiner. (n.d.). Office of the medical examiner 2016 calendar year annual report. Retrieved from https://justice.ky.gov/Documents/Medical%20Examiners/2016%20ME%20Annual%20Report%20FINAL.pdf

Penfold, R. & Zhang, Z. (2013). Use of interrupted time series analysis in evaluating health care quality improvements. Department of Health Services Research. S39-S44. doi: 10.1016/j.acap.2013.08.002

Pitt A., Humphreys, K., & Brandeau, M. (2018). Modeling health benefits and harms of public policy responses to the US opioid epidemic. *American Journal of Public Health, 108*(10), 1394-1400. doi: 10.2105/AJPH.2018.304590

Rothberg, R. & Stith, K. (2018). Fentanyl. *The Journal of Law, Medicine & Ethics, 46*, 314-324. doi: 10.1177/1073110518782937

Sarpatwari, A., Sinha, M., & Kesselheim, A. (2017). The opioid epidemic: Fixing a broken pharmaceutical market. *Harvard Law & Policy Review, 11*, 463-484. Retrieved from http://harvardlpr.com/wp-content/uploads/2017/07/SarpatwariSinhaKesselheim.pdf.

Skinner, B. F. (1938). *The Behavior of Organisms: An Experimental Analysis*. New York, NY: Appleton-Century-Crofts.

Smith, M. (2018). What do these political ads have in common? The opioid crisis. Retrieved from https://www.nytimes.com/2018/06/07/us/opioid-ads-democrats-republicans.html

Tabachnick & Fidell (2013). *Using multivariate statistics*. Boston, MA: Pearson.

Tilley, J. C., & Ingram, V. (n.d.). 2016 overdose fatality report. Frankfort: Kentucky Office of Drug Control Policy.

Trickey, Erick (2018). Inside the story of America's 19th century opiate addiction. Retrieved from https://www.smithsonianmag.com/history/inside-story-americas-19th-century-opiate-addiction-180967673/

Unick, G., Rosenblum, D., Mars, S., Ciccarone, D. (2014). The relationship between US heroin market dynamics and heroin-related overdose, 1992-2008. *Addiction, 109*(11), 1889-1898. doi: 10.1111/add.12664

United States Department of Health and Human Services. (n.d.a). What is the U.S. opioid epidemic? Retrieved from https://www.hhs.gov/opioids/about-the-epidemic/index.html

United States Department of Health and Human Services (n.d.b). *Addressing prescription drug abuse in the United States: Current activities and future opportunities.* Retreived from https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf

U.S. National Library of Medicine. (n.d.). Opiate and opioid withdrawal. Retrieved from https://medlineplus.gov/ency/article/000949.htm

Van Hout, M.C. (2014). "Doctor shopping and pharmacy hopping": Practice innovations relating to codeine. *Drugs and Alcohol Today, 14*(4), 219-234. doi: 10.1108/DAT-03-2014-0014

Volkow, N. (2014). America's addiction to opioids: Heroin and prescription drug abuse. Retrieved from https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2018/americas-addiction-to-opioids-heroin-prescription-drug-abuse

Wagner, A., Soumerai, S., Zhang, F., and Ross-Degnan, D. (2002). Segmented regression analysis of interrupted time series studies in medication use research. *Journal of Clinical Pharmacy and Therapeutics*, *27*, 299-309. doi: 10.1046/j.1365-2710.2002.00430.x

White, C., Ready, J., & Katz, C. (2016). Examining how prescription drugs are illegally obtained: Social and ecological predictors. *Journal of Drug Issues, 46*(1), 4-23. doi: 10.1177/0022042615608502

WLKY News Louisville. (2016). Complete video: U.S. Attorney General Loretta Lynch town hall in Kentucky. Retrieved from https://www.youtube.com/watch?v=aRUWSz-EqJ4

Wright, J. (2011). A history of opium, from medical to recreational use. *British Journal of School Nursing, 6*(10), 512. Retrieved from https://ezp.waldenulibrary.org/login?url=https://search.ebscohost.com/login.aspx?direct=true&db=edb&AN=70360537&site=eds-live&scope=site

Wright, J. (n.d.). Oxford Bibliographies: Rational choice theories. Retrieved from http://www.oxfordbibliographies.com/view/document/obo-9780195396607/obo-9780195396607-0007.xml

Yaffee, R. and McGee, M. (2000). *An Introduction to Time Series Analysis and Forecasting: With Applications of SAS and SPSS*. Cambridge, MA: Academic Press.

Appendix A

For the ARIMA(0, 1, 0) model, a significant ACF was found in lag 1 ($p = 0.047$, Table A3) and hence the assumption of independence of residuals was violated. For the ARIMA(1,1,0) model, the normality assumption was violated (Table A2).

Table A1.

Results of ITS Analysis of Mortality of Opioids

		Coefficient	*SE*	*t*	*p*	R^2
ARIMA(0, 1, 0)	Intercept (β_0)	-8.000	21.091	-.379	.718	0.673
	Baseline trend (β_1)	6.000	5.740	1.045	.336	
	Level change after intervention (β_2)	-40.667	16.066	-2.531	.045	
	Trend change after intervention (β_3)	.143	6.509	.022	.983	
ARIMA(1, 1, 0)	Intercept (β_0)	-8.828	16.110	-.548	.607	0.776
	Baseline trend (β_1)	5.826	4.433	1.314	.246	
	Level change after intervention (β_2)	-37.672	12.253	-3.074	.028	
	Trend change after intervention (β_3)	.139	4.602	.030	.977	

Note: *SE* = standard error, *t* = *t* statistic, *p* = *p* value.

Table A2.

Results of Shapiro-Wilk Tests

	W	*df*	*p*
ARIMA(0, 1, 0)	0.953	10	0.699
ARIMA(1, 1, 0)	0.765	10	0.005

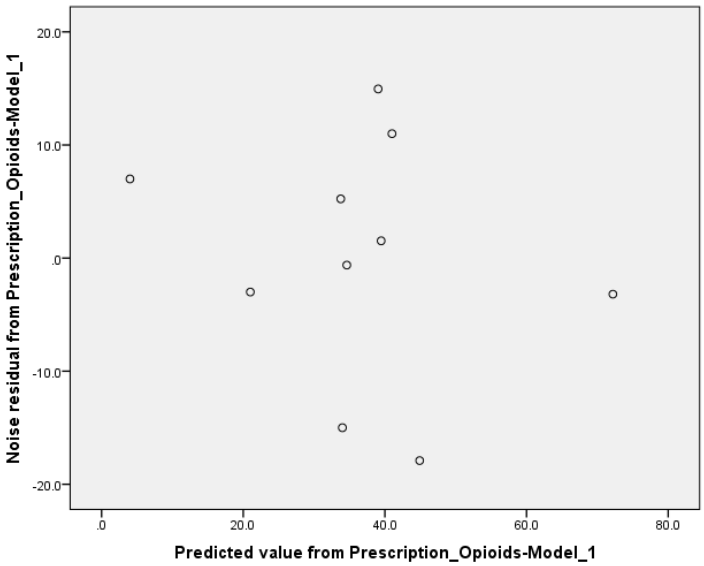

Figure A1. Plot of standardized residuals and predicted values (ARIMA(0, 1, 0)).

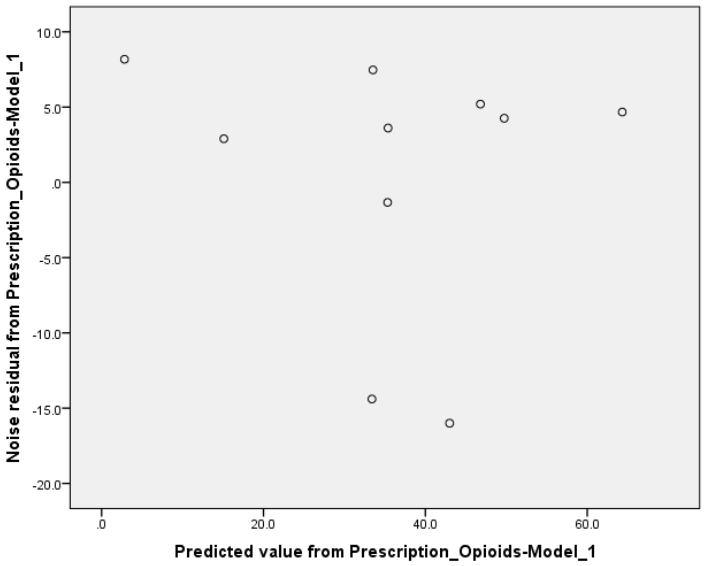

Figure A2. Plot of standardized residuals and predicted values (ARIMA(1, 1, 0)).

Table A3.

ACFs and PACFs for the Residuals

				Box-Ljung statistic				
	Lag	Autocorrelation	*SE*	Value	*df*	*p*	Partial autocorrelation	*SE*
ARIMA (0, 1, 0)	1	-.544	.316	3.944	1	.047	-.544	.316
	2	-.013	.399	3.947	2	.139	-.439	.316
	3	.087	.399	4.077	3	.253	-.285	.316
	4	-.241	.401	5.239	4	.264	-.624	.316
	5	.413	.415	9.330	5	.097	-.332	.316
	6	-.171	.454	10.207	6	.116	-.186	.316
	7	-.124	.461	10.820	7	.147	-.240	.316
	8	.116	.464	11.621	8	.169	-.257	.316
ARIMA (1, 1, 0)	1	-.254	.316	.860	1	.354	-.254	.316
	2	-.329	.336	2.481	2	.289	-.420	.316
	3	-.020	.367	2.488	3	.477	-.319	.316
	4	-.083	.367	2.626	4	.622	-.506	.316
	5	.424	.369	6.944	5	.225	.073	.316
	6	-.078	.415	7.125	6	.309	-.041	.316
	7	-.268	.416	9.990	7	.189	-.062	.316
	8	.059	.433	10.198	8	.251	-.028	.316

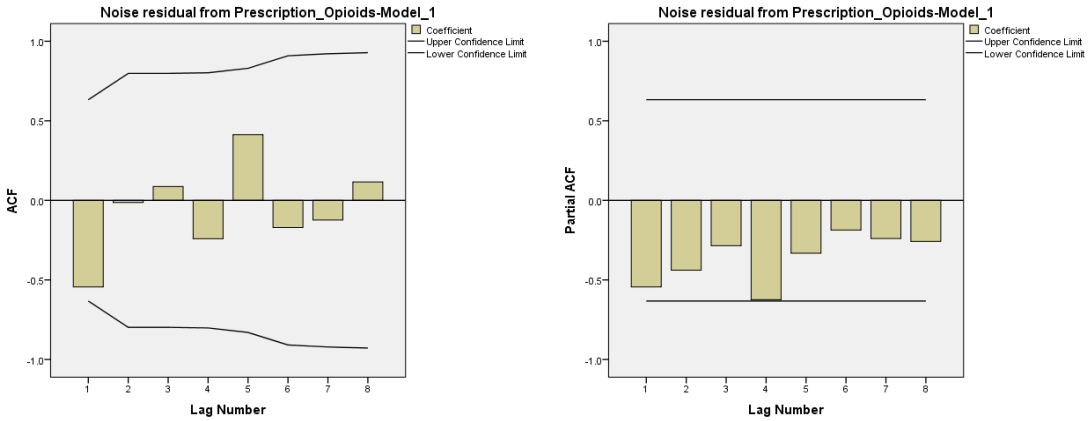

Figure A3. Figures of ACFs (right) and PACFs (left) for the residuals (ARIMA(0, 1, 0)).

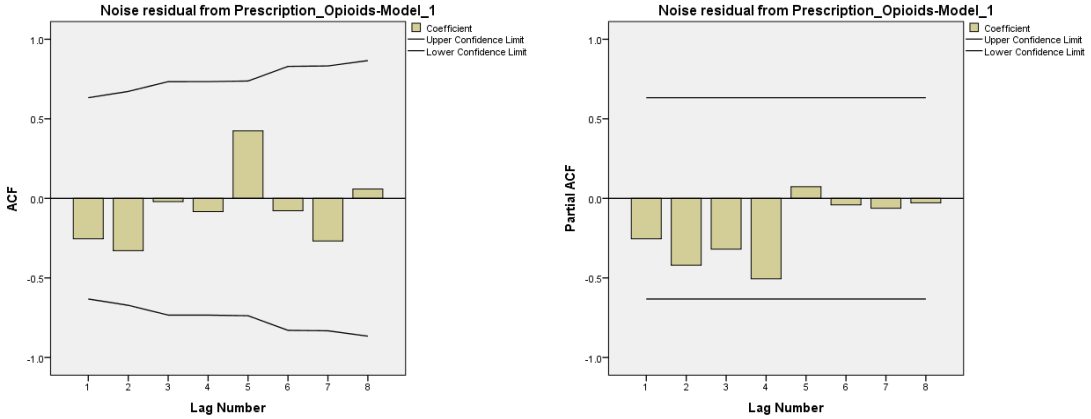

Figure A4. Figures of ACFs (right) and PACFs (left) for the residuals (ARIMA(1, 1, 0)).

Appendix B

For the ARIMA(0, 1, 0), ARIMA(1, 1, 0), ARIMA(1, 1, 1) models, the normality assumption was violated (Table B2).

Table B1.

Results of ITS Analysis of Mortality of Opioids

		Coefficient	*SE*	*t*	*p*	R^2
ARIMA(0, 1, 0)	Intercept (β_0)	-9.600	45.567	-.211	.840	0.938
	Baseline trend (β_1)	3.600	12.402	.290	.781	
	Level change after intervention (β_2)	-27.667	34.710	-.797	.456	
	Trend change after intervention (β_3)	14.429	14.062	1.026	.344	
ARIMA(1, 1, 0)	Intercept (β_0)	-8.809	50.566	-.174	.869	0.938
	Baseline trend (β_1)	3.314	13.739	.241	.819	
	Level change after intervention (β_2)	-26.408	38.619	-.684	.524	
	Trend change after intervention (β_3)	14.601	15.714	.929	.395	
ARIMA(1, 1, 1)	Intercept (β_0)	-15.182	54.722	-.277	.795	0.947
	Baseline trend (β_1)	-.994	32.891	-.030	.977	
	Level change after intervention (β_2)	5.498	14.540	.378	.725	
	Trend change after intervention (β_3)	-37.993	40.013	-.950	.396	

Note: *SE* = standard error, *t* = *t* statistic, *p* = *p* value.

Table B2.

Results of Shapiro-Wilk Tests

	W	*df*	*p*
ARIMA(0, 1, 0)	.788	10	.010
ARIMA(1, 1, 0)	.765	10	.005
ARIMA(1, 1, 1)	.791	10	.011

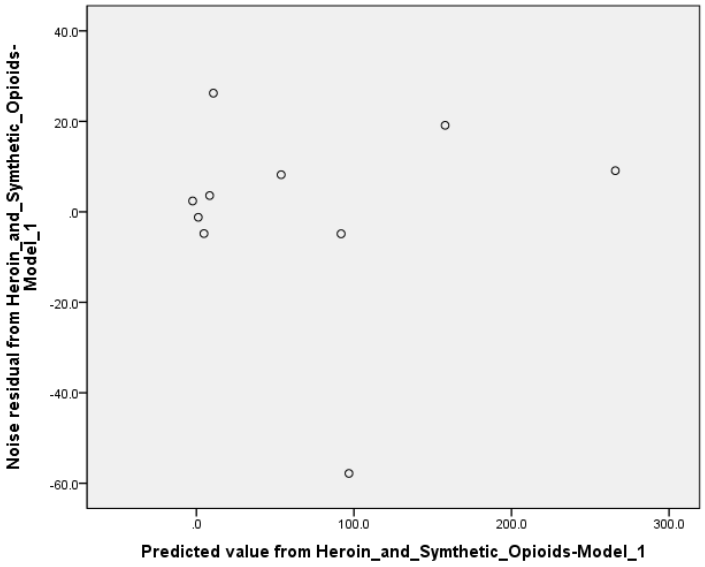

Figure B1. Plot of standardized residuals and predicted values (ARIMA(0, 1, 0)).

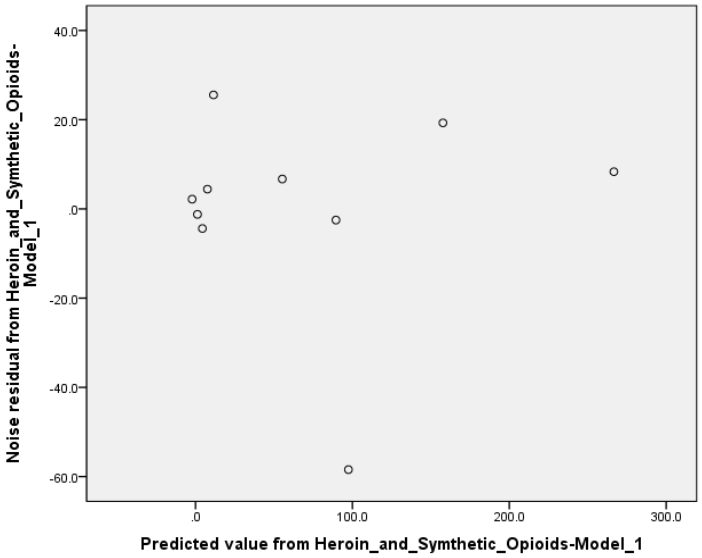

Figure B2. Plot of standardized residuals and predicted values (ARIMA(1, 1, 0)).

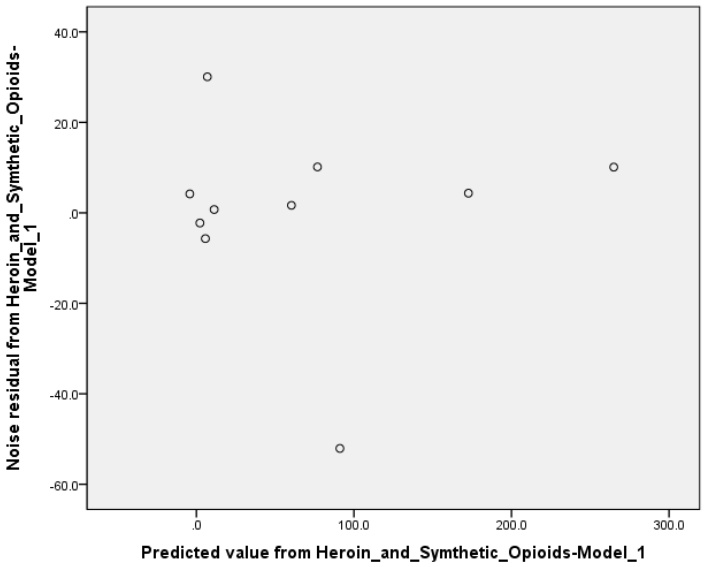

Figure B3. Plot of standardized residuals and predicted values (ARIMA(1, 1, 1)).

Table B3.

ACFs and PACFs for the Residuals

				Box-Ljung statistic				
	Lag	Autocorrelation	*SE*	Value	*df*	*p*	Partial autocorrelation	*SE*
ARIMA (0, 1, 0)	1	.040	.316	.021	1	.885	.040	.316
	2	-.611	.317	5.620	2	.060	-.613	.316
	3	-.166	.418	6.093	3	.107	-.165	.316
	4	.193	.425	6.836	4	.145	-.289	.316
	5	.091	.433	7.035	5	.218	-.212	.316
	6	-.042	.435	7.087	6	.313	-.203	.316
	7	-.017	.436	7.098	7	.419	-.166	.316
	8	.008	.436	7.102	8	.526	-.175	.316
ARIMA (1, 1, 0)	1	.029	.316	.011	1	.915	.029	.316
	2	-.598	.316	5.381	2	.068	-.600	.316
	3	-.159	.414	5.814	3	.121	-.177	.316
	4	.183	.420	6.483	4	.166	-.283	.316
	5	.086	.428	6.660	5	.247	-.215	.316
	6	-.037	.430	6.702	6	.349	-.203	.316
	7	-.014	.430	6.710	7	.460	-.167	.316
	8	.007	.430	6.713	8	.568	-.174	.316
ARIMA (1, 1, 1)	1	-.116	.316	.181	1	.671	-.116	.316
	2	-.479	.320	3.620	2	.164	-.499	.316
	3	-.083	.385	3.738	3	.291	-.304	.316
	4	.146	.387	4.166	4	.384	-.269	.316
	5	.096	.393	4.386	5	.495	-.195	.316
	6	-.065	.395	4.513	6	.608	-.235	.316
	7	-.007	.396	4.515	7	.719	-.139	.316
	8	-.002	.396	4.515	8	.808	-.182	.316

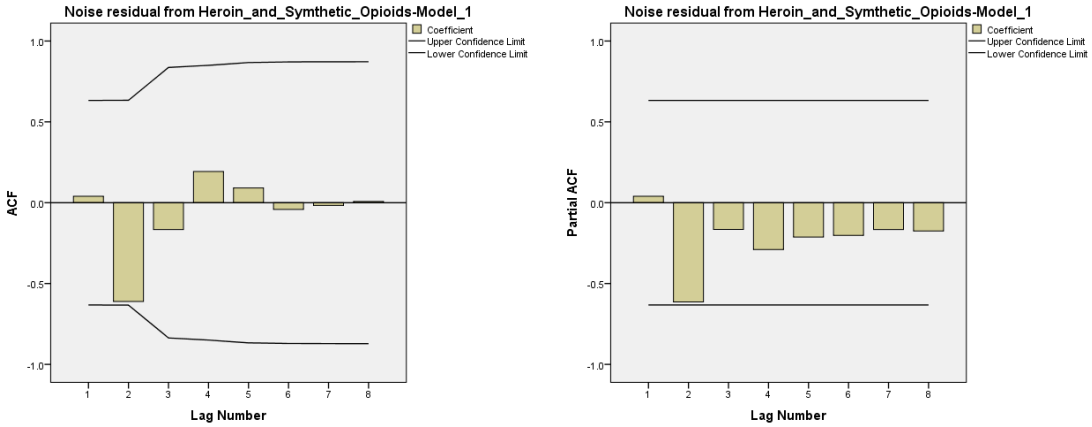

Figure B4. Figures of ACFs (right) and PACFs (left) for the residuals (ARIMA(0, 1, 0)).

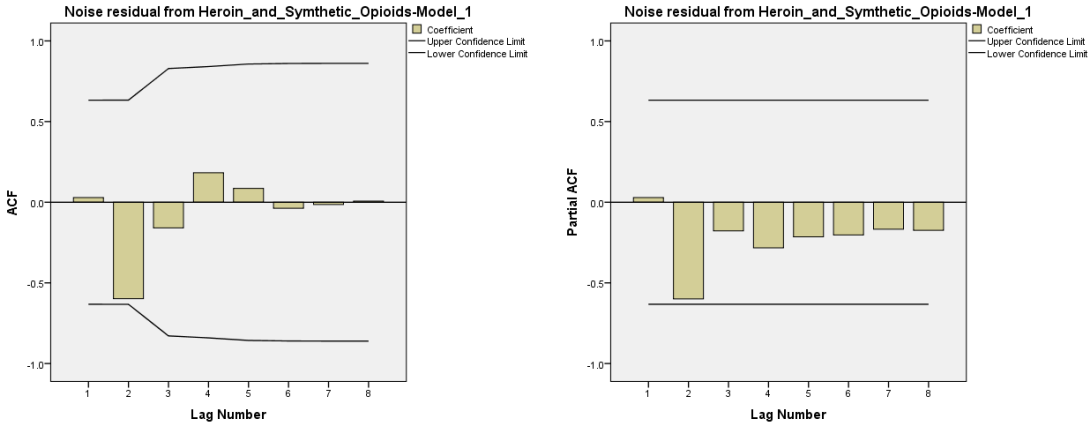

Figure B5. Figures of ACFs (right) and PACFs (left) for the residuals (ARIMA(1, 1, 0)).

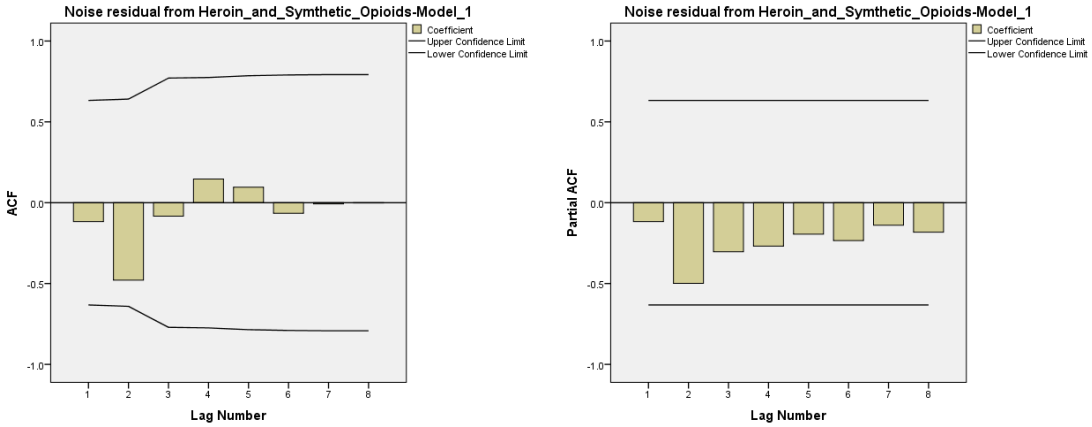

Figure B6. Figures of ACFs (right) and PACFs (left) for the residuals (ARIMA(1, 1, 1)).