

**THE PDMP VIRTUAL WAR ON OPIOIDS EPIDEMIC IN THE U.S.:
A COMPARATIVE QUANTITATIVE ANALYSIS OF THE SYSTEM'S
INTEROPERABILITY, CAUSALS & EFFECTS**

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ABSTRACT

For a decade, the United States witnessed a significant increase in drugs' prescriptions, especially opioids/narcotics, which created new crisis threatening the population's health. Many reasons contributed to this phenomenon such as overprescribing, overusing, and misusing, where many parties have a stake in the outcomes, including physicians. In 2011, and due to the increase of unlawful use and drugs' overdose fatalities, many health organizations, private and public, joined forces to develop an electronic and centralized database system where drugs' prescriptions can be carefully monitored and managed by healthcare professionals, known as the Prescription Drug Monitoring Program (PDMP). Since then, much research was conducted to assess PDMP's outcomes. However, this study serves as a follow-up and an identifier of any changes in the PDMP effects after it became a mandatory in 47 states. Within this process, the study will address the role of the Planned Behavior Theory behind utilizing and scaling PDMP at the national level. A quantitative research method is applied as a comparative analysis of case studies conducted from 2009 to date on the causes and effects of using PDMP, followed by a survey to validate and report any outcomes' changes.

Keywords: Prescription Drug Monitoring Program, Epidemic, Opioid Prescription, Electronic Medical Records, Drug Overdose, Theory of Planned Behavior, Database Technology, Technology Integration

INTRODUCTION

For long, the world has identified diseases that spread quickly and affect the population within a period, such as 'Cholera' in Africa. When a disease spreads from one person to another, it becomes an epidemic which requires multiple scientific disciplines to become engaged in the pursuit of treatment. Within the last few years, the opioids' use in the United States alone reached an uncontrollable majestic rate. Many factors contributed to this such as, the overprescribing by physicians, patients' refusal to comply with physicians' and pharmacists' recommendations on using alternative drugs for pain management, including Selective Serotonin Reuptake Inhibitors (SSRIs), known as antidepressants chemical agents that work by increasing levels of serotonin in the brain. Medical research proved that SSRIs are useful for patients with chronic pain. Yet, certain chronic pain conditions are beyond the control of SSRIs or over-the-counter pain relief, drugs such as Tylenol and Motrin, but somehow manageable with opioids, such as oxycodone and morphine. Unfortunately, after years of use, patients become highly-dependable on opioids. And in many cases, individuals with opioids addictions refuse to seek professional help to overcome their addiction.

The term addiction in this scenario refers to those who take a drug and then become dependable on it. As soon as the use of opioids prolongs beyond the 30 days, patients begin to experience awkward personalities when not using the opioid, and when the doctor refuses to re-issue the opioid prescription, the patient seeks to switch between physicians until one prescribe it again. On the other hand, patients who fail to obtain opioids from their family doctor become frequent visitors to the emergency room departments with fake problems just to secure an opioid prescription. This situation led many healthcare providers to depend on their judgment and prescription habits for a patient as he or she requests more opioid prescriptions.

Unfortunately, the situation of opioids' abuse caused many patients with real problems to be mistaken for those who don't, resulting in under-treatment and mismanagement of pain. Many hospitals and physicians described this epidemical phenomenon as the worse in the history of medicine and epidemical diseases, and that is due to the rising numbers of deaths from drug overdose. In 2015, a study found that there are more than 12.5 million people misused prescription opioids, more than 33,091 died from opioids' overdose, two million with prescription opioid use disorders, 828,000 people used heroin, 135,000 people used heroin of which caused more than 12,989 deaths. Overall, the opioids

prescribing and use in the United States cost over \$78.5 billion (Finklea, Sacco, & Bagalman, 2014).

RESEARCH QUESTIONS

In this study, I hypothesized that the existence of the Prescription Drug Monitoring Program has tremendously impacted the prescription drugs processes, behavior, and volume in the U.S., and saving the lives of thousands each year. However, to support this, it is essential to conduct this research as an expansion to previous studies done on the causes leading to the invention of the PDMP technology, since it still emerging and expanding, and its effects within the content of the following proposed research questions:

1. What are the current changes impacting the PDMP database system's operational design with the rise of the opioids' crisis in the United States?
2. Which components of prescribing, dispensing, and using opioids have been impacted the most after making PDMP database's utilization mandatory in 49 states in the U.S., especially the overall population's health?
3. How does the new integrated structure of the PDMP database support its purpose and goals?
4. What role does the Theory of Planned Behavior have in the implementation of PDMP across states?
5. Which clinical indicators or measures have been used to assess the PDMP information's flow processes and outcomes? Including the role of Appriss' PDMP, Narxcare Program used at states level?

DEFINITION OF PDMP AND OPIOID DRUGS

Due to opioids' crisis in the United States today, including opioids' overdose, abuse, misuse, addiction, and diversion, it is essential to define the Prescription Drug Monitoring Program (PDMP) and its solutions. The PDMP, as defined by the American Academy of Pediatrics, is an "electronic database that collects data on controlled substance prescriptions dispensed by a state." The PDMP abbreviation used throughout the study refers to the primary database source that feeds each state's PDMP system with information on patients' prescriptions records, especially opioids' use. The term "Opioid" is used interchangeably with "prescription drugs" throughout the study. Opioids or narcotic prescriptions are identified by the Food and Drug Administration (FDA) as class IV substances, such as Heroin, Hydrocodone (Vicodin), Morphine, Oxycodone (OxyContin), Diazepam, and many others, used for the treatment of short-term and chronic pains (Reisman, Shenoy, Atherly, and Flowers, 2009).

LIMITATIONS

This study focuses only on the health and prescription division within PDMP, especially the prescription drugs' and substance abuse; not its programs available for retail industry or law enforcement. The last will be identified just to touch base on the magnitude of PDMP role nationwide. Also, due to the nature of the data collected for this study; using previous studies' outcomes, presents a limitation in the scope of findings. Therefore, a future research using other methods than case studies is preferred to expand on the understanding in the shift of events related to prescription drugs' monitoring effects on healthcare organizations, healthcare insurance payers, and patients.

LITERATURE REVIEW PDMP DATABASE OPERATIONAL DESIGN CHANGE, PURPOSE, CAUSATION & EFFECTS

In a 2009 study, the National Institute of Health (NIH) found that in PDMP affiliate states, the oxycodone shipments quantities and opioids' admission rates appeared to be decreasing. However, the opioids' shipments from 1997 to 2003 increased significantly due to physicians' prescribing habits causing this "negligible effect" (Reisman, Shenoy, Atherly,

and Flowers, 2009. In the last couple of years, the prescription drugs' abuse or misuse in the United States became a significant threat requiring the intervention from healthcare professionals and official authorities to expand their monitoring and investigating practices to control the opioids' crisis in the U.S. Today, 4.3 million Americans reported non-medical use of prescription drugs.

In 2015, the National Survey on Drug Use and Health (NSDUH) reported the following: 91.8 million (37.8%) U.S. civilian, noninstitutionalized adults used prescription opioids, 11.5 million (4.7%) misused opioid prescriptions, 1.9 million (0.8%) had a use disorder, 59.9% reported using opioids' drugs unlawfully and without prescription, and 40.8% obtained prescription opioids for free from friends or relatives. Every day, 91 Americans die from opioids overdose, totaling ½ million who died from 1999 to 2015, ranging 6 out of 10 people on opioids die from Opioids' overdose (Griffin, 2017).

The first step of monitoring opioids' prescriptions begins with the integration of the Prescription Drugs Monitoring Program database (PDMP) at the state and healthcare organizational levels. The PDMP, as defined by the American Academy of Pediatrics in 2016, is "an electronic database that collects data on controlled substance prescriptions dispensed within a state" (Fleming, Barner, Brown, Shepherd, and Strassels, 2014). However, for health reasons, the PDMP came into existence as a revolutionary technology that monitors: Which prescription drug? What quantity? And by who? How often? Who dispense it? And When? How patients' use it? And if there any signs of addiction or unlawful misuse? The misuse of prescription drugs turned into a crisis in the U.S. shielding the opioids' hidden-epidemic that risks the public health in general, and the lives of millions of people specifically in the U.S. alone. Beyond the fact that the U.S. has been experiencing an increase in the number of fatalities due to opioids' overdose, these drugs led to significant increase in the cost of health and criminal justice systems in the United States (Fox & Felkey, 2017). As determined by the National Institute on Drug Abuse in 2017, among many outcomes of prescription drugs' misuse, opioids alone cause approximately more than 90 Americans to die each day (Smith, Jones, Katz, Roland, and Setnik, 2017). This phenomenon called for states' officials, healthcare professionals, and authorities to identify their responsibilities and join forces to take a role in turning the situation around and protect the public health whatever it takes. For example, in the state of Pennsylvania, PDMP became a legislation and went into full-effect in 2016, mandating all providers to use it for reporting (Westgate, 2017). The efforts were mainly-directed to mandating the use of the PDMP in each state and by each provider and pharmacist. The PDMP, state or national, has three primary purposes including:

1. Supports the early prevention of prescription drug abuse.
2. Provides historical background on a patient's use of prescription drugs' abuse to indicate if there is a need for intervention.
3. Serves as a warning system for providers to avoid drug interactions.

The initial PDMP system process is simulated in Figure 1 which shows the PDMP operational system and transactional flow. The way the process works is that after physicians and pharmacists update the patient's medication list or after ordering a new drug for treatment, the information immediately stores in the EMR, which later gets exported (by reporting) to the PDMP system of the state, which also then gets reported to the national PDMP. The most simplified version of how PDMP system functions relates to how PDMP collects information which lay within this structure. Unfortunately, to date, some patients are still trying to jump between providers in pursuit of more quantities of the opioid drug(s). In many instances, that behavior is not related to their need to control their pain symptoms, in contrary, it is more related to the patient's intentions in unlawfully resell the pills on the street. Unfortunately, school and college students are among the majority population who the targeted in this situation, as they are more vulnerable than professional working class.

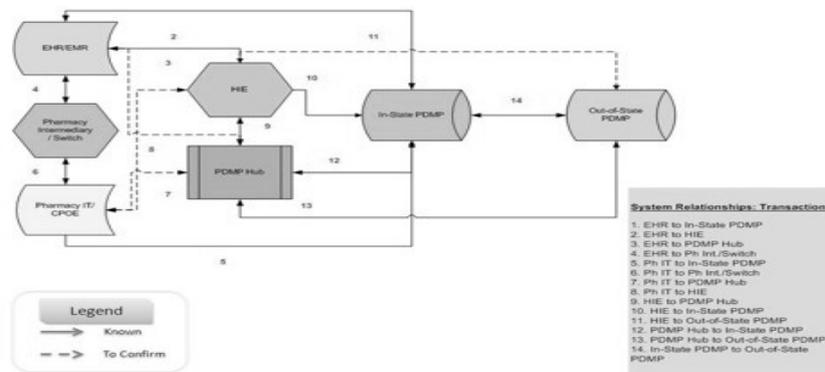


Figure 1. The PDMP Operational System and Transactional Flow
 Source: Flinklea, Sacco, and Bagalman (2014)

The pilot structure of the PDMP database design was proven weak. Therefore, efforts were made to integrate PDMP exchange architecture solution plan using multi-level standards. Therefore, innovating the states' PDMP became urgent. Today, the modified process seems efficient and agile for healthcare professionals involved.

In its early stages, the PDMP database design model was more straightforward than it is today. However, the rapid growth of information technologies led to revisiting and modify the program's structure. Figure 2 shows an updated PDMP data architecture design. The newer model divides the processes of monitoring the prescribing, dispensing, and using opioids into four categories: (1) The source system, (2) The data harmonization, (3) The health IT and clinical database, and finally, (4) The user interface presentation. (Finklea, Sacco, & Bagalman, 2014). Each category has two or more sub-categories. Level one of the new PDMP design structure begins with the source systems such as the state's PDMP, the state's Health Information Exchange, and PDMP, and other medications history sources. In the second level, data harmonization takes place to store data within the organization PDMP like software. In this level, the information is extracted and transformed to move upward to reach pharmacies' health information systems, and then automatically updates within the central hub get distributed the same information across the state making data available at the healthcare professionals' fingertips. The data required in the third level comes from the Electronic Health Records and pharmacy IT application which uses medical history and reconciliation, Electronic Prescribing (ePrescribing), and internal medical orders (Finklea, Sacco, and Bagalman, 2014).

Figure 2 shows the PDMP's new and integrated data exchange architecture and solution plan-multi-level standards. The process begins with physicians and pharmacists entering data into their electronic system, reporting the data with the state's PDMP platform, which then gets transferred to a national PDMP centralized database. The information gets transferred back-and-forth between all three when needed. For example, doctors can initiate queries within their electronic records that are interfaced with the centralized PDMP to gather data about a patient prescriptions' list from any state, except Missouri. However, prior to issuing any new opioid prescription and others known to negatively interact with other drugs, cause major side effects, or even lead to death; a process that is extremely rigorous, yet effective in changing the status of prescription prescribing in the U.S. For example, when a prescription is needed or requested by a patient, especially opioid prescription, the physician has a responsibility of requesting a report from PDMP that presents the history of what prescription drugs has the patient been receiving, when he or she received them, who prescribed them, and the quantity. If cleared, the prescription order gets placed. With the old system, three copies of the prescription get printed, one to keep at the practice, and two given to the patient to hand-deliver to the pharmacy where one gets filled in the pharmacy records, and the other gets sent and stored in the state's database. Following those steps lead the health system to report its opioids prescriptions using secure process for health information exchange, which then submit its data and reports electronically to three different PDMPs including the state PDMP, out-of-state PDMP, and finally all report to the PDMP hub database where all data is stored and then securely used by other states, doctors, and patients (Foxhall, 2010). For example, exchanging information between the state of New York and the state of Pennsylvania as if they feed on each other. What's unique about this service is that every healthcare organization or individual must report to state the status of opioids' prescriptions issued by the doctors, and dispensed by pharmacists. These reports are transmitted electronically to three different PDMP systems including, the state PDMP, out-of-state PDMP, and finally all report to the PDMP hub and the parent database where all data is stored and then used by other states (Finklea, Sacco, and Bagalman, 2014).

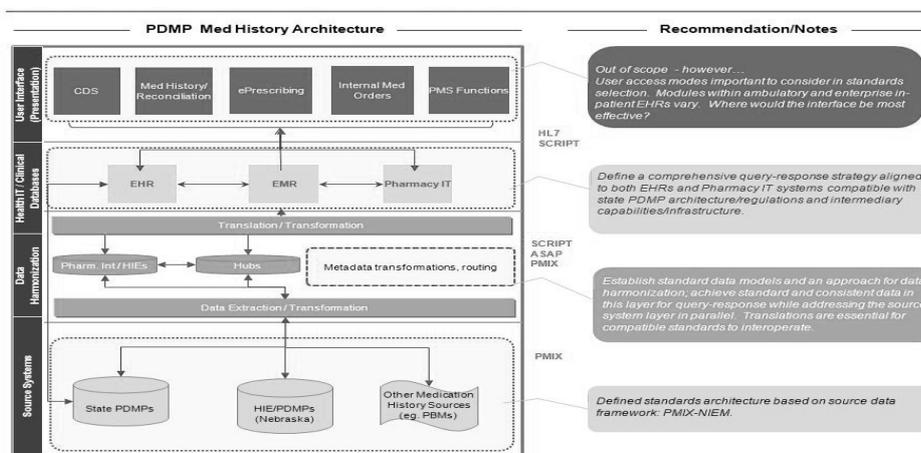


Figure 2: Integrated PDMP Data Exchange Architecture and Solution Plan-Multi-Level Standards
 Source: Finklea, Sacco, and Bagalman (2014)

Today, all prescriptions must be emailed directly to the pharmacy using code identifiers of the ordering physician. This modification eliminated the third-party involvement where most of the prescriptions' theft happened. For example, when a doctor gives Mary a prescription of 120 pills of Hydrocodone for her back-injury pain, Mary may ask a family member or a friend to hand-deliver the prescription to the pharmacy. That individual may or may not be trustworthy when it comes to narcotic prescription. Over time, this process led many people to have unlawful access to opioid prescriptions. For this stand alone, many states and national health legislation, including the PDMP and the Food and Drug Administration (FDA) (Finklea, Sacco, and Bagalman, 2014), seek more sophisticated and well-defined process for handling prescription drugs from the time the doctor prescribes the drug to the time it reaches the patient. With this new process, the PDMP helped physicians identify those patients with drug abuse so they can decide to either:

1. Notify patients of their knowledge about their drug dependency or addiction problem.
2. Inform patients of the risks associated with its use, provide alternative drugs that are safer.
3. Offer patients help options supported by hospitals' and rehabs who can assist them in close monitoring and manage the withdrawal symptoms of the drug (Brauser, 2015).

As a system, the PDMP database is provided and supported by many software vendors in the U.S. However; the most popular is Appriss Health, Louisville, KY, through its Narxcare PDM Database Platform - "a drug monitoring program to access state data of controlled substance prescriptions" (Arndt, 2017), Appriss Health PDMP helps physicians, pharmacists, and other healthcare organizations analyze information extracted from its database to make informed decisions for intervention and healthcare management outcome using its industry's most efficient and effective leading clinical data analytics for supporting clinical decision solutions. Appriss Health partners and customers in health can better analyze data, anticipate outcomes, investigate in pursuit of solutions for issues facing health, retail and law enforcement sectors (Griffin, 2017). This study focuses only on the health division, the Narxcare Database Platform for PDMP, which is "A comprehensive substance use disorder platform with powerful analytics for risk assessment and patient support tools" (Arndt, 2017).

The structure of the PDMP follows a clear pattern that the healthcare organizations, the states, and healthcare providers can relate to within their work environment. Figure 3. shows the design laid for PDMP interoperability. It starts with pharmacists entering prescription orders into the pharmacy technology software, and then report them to the PDMP that correspond back to pharmacists and healthcare providers. Once data is stored in the PDMP Hub, various subjects become part of this process due to having some interest in the situation. For example, State Insurance Programs have interest in reducing their cost of prescription drugs and apply preventive health measures to improve the population's health. Another party, such as government healthcare agencies, like the State Health Department, may have similar or different goals regarding the U.S. population health and disease management. Also, Law Enforcement agencies also have interest in keeping individuals attempting to unlawfully distribution and sale of prescription painkillers off the streets. Over time, these efforts will pay off with consistency and careful monitoring. Finally, physicians across the board are becoming more cautious and rigorous when it comes to prescribing drugs, and PDMP made the process for them very easy, in addition to supporting their decision-making process (Finklea, Sacco, and Bagalman, 2014).

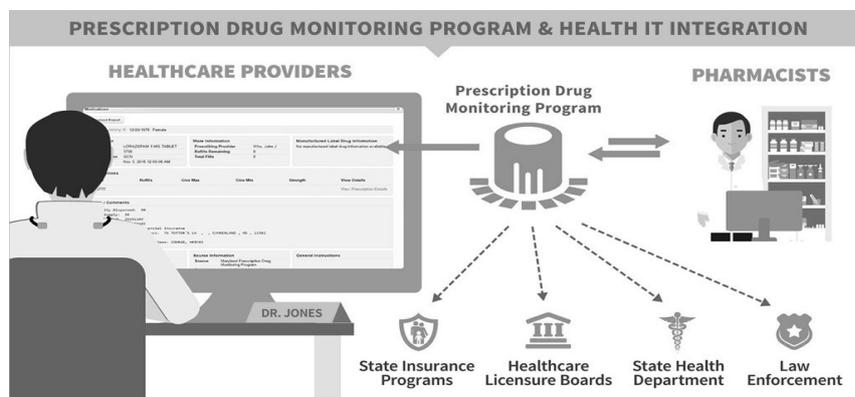


Figure 3. PDMP Interoperability and Health IT Integration
Source: Finklea, Sacco, and Bagalman (2014)

The PDMP to date, changed many areas of medical management and safety measures such as:

1. *Enhancing patients' safety* through its alerts on drug interactions, duplicate therapy treatments, and dosing mistakes.
2. *Improvement of accuracy* when prescribing opioids due to the use of electronic medical records.
3. *Reduction in drug and fraud diversion* by designing a secure system that secures the flow of prescriptions between physicians and pharmacists, and hence, eliminate risks of alteration or forgery that took place during the era of paper prescriptions.
4. *Reduce*, or if possible, *eliminate opioids' abuse and misuse* through proper and honest reporting.
5. *Improve physicians' prescribing habits and workflow processes* by mandating the use of one workflow system such as EMR (Bao, Pan, Taylor, Radakrishman, and Luo, 2016).
6. *Improve the general health of the U.S. population* (Reisman, Shenoy, Atherly, and Flowers, 2009).

With such outcomes, the most important is to identify whether the mandated use of the PDMP system today has changed the status of opioids' crisis and whether the prescribing, dispensing, and using prescription drugs behaviors have significantly improved in the United States (Brauser, 2015). Finally, this study will assess physicians' and pharmacists' knowledge on prescription drugs' disposal and determine how the Theory of Planned Behavior (TPB) support their intentions to educate their patients about the drug's side effects, its risks on their health, and possible dependability (Tai, Hata, Wu, Frausto, and Law, 2016). This study adds value to the theory by examining an additional behavior from physicians, especially after making PDMP a legislation, regarding the refusal of prescribing and the actions, are taken in this case.

METHODS AND PROCEDURES

This study includes two participants, the first consists of 20-30 physicians from various medical facilities. Most physicians who prescribe opioids are primary care doctors since they are the primary prescribing source of opioids' related drugs, and the second includes are (Laser, 2017) pharmacists within and outside a hospital system.

This study also uses a comparative analysis between the literature on the causals and effects of implementing the PDMP by nearly all states, except Missouri, and the results of the self-administered survey, which will be emailed or mailed to all participants. The survey instrument, using Survey Monkey, will focus on gathering up-to-date information based on five categories including:

1. Physicians' and pharmacists' perceptions of the PDMP today on a scale of 1 to 5 where 1 is "made no difference," and 5 is "made a difference.
2. Physicians' and pharmacists' opinions about the usability and functions of the PDMP database system, and if it supports their clinical-decision processes. For example, is PDMP today more agile, effective, and in support of their clinical decisions. Also, did the communication in this matter improved or not.
3. Changes in the trends of patients with drug abuse since PDMP became a legislation in the state of Pennsylvania. In this section, percentages are significant even though the sample is small. Example, what is the reduction percentage of opioids' prescriptions? And are patients informed about the reports, and how physicians are handling problems with patients who insist on receiving the drugs?
4. The PDMP effects on improving the overall health of the population. For example, decrease in prescriptions' side effects, improvement in physical and mental symptoms; knowing that muscular pain and depression are among the symptoms initiated by opioids' use.
5. Physicians', pharmacists' and patients' behavioral change in term of prescribing or dispensing or using prescription opioids. This category is intended to identify new behavioral changes that can impact the Theory of Planning Behavior.

Each category will have a group of two to three questions using Likert-like scales. Each item in the survey must correspond with the findings of causals and effects of PDMP from previous studies. Upon completion, all responses will be entered in an excel spreadsheet. Using SPSS statistical software, descriptive statistics will be reporting each of the survey items. This study will use the Pearson correlation methods to confirm the reliability of the survey method. Also, analyzing which variable a significant for the results. Other methods of statistical analysis, such as the mean, the median, the standard deviation, and the maximum, will be determined to compare the results with those from the literature.

RESEARCH RESULTS

The results of the data show that more than 85 percent of physicians believed that the PDMP system makes a big difference in how they improved the population health. On the other hand, 91 percent of pharmacists perceived the system as the best to control the opioids epidemic and reduce the mortality rates. Also, over 90 percent of both groups agreed that PDMP system is user-friendly and agile. Any individual in both groups seemed to have adequate knowledge about the usability of the system to reach the goal of opioid prescription control. The most noticeable result was that despite the feasibility and usability of the PDMP system, over 62 percent of physicians raised different type of concerns about a group of patients who reject the new approach of limited prescriptions of opioids' pills for the treatment of chronic pain, and refusing the proper rehab treatment due to their addictive behavior. Physicians felt that they apply the maximum effort to hand the patient's insistence on her/his demand for opioids. Overall, the PDMP system allowed for the reduction of more than 50 percent in the prescribing of opioids' drugs. Even though there is a noticeable number of clinicians in both groups who believe that the system is helpful, it helped them have stronger urge to control the ordering of opioids; regardless of the federal agencies enforcement policies to manage and control of the type and quantity of opioids prescribed to each patient. Overprescribing any of the opioids led to revolutionary behavioral change among clinicians, which ultimately led to better outcomes and opened the door to various treatment approaches that are meant to reduce the dependency on the drugs. PDMP's prescribing behavior have to change the way physician operates. For a long time, physicians had attempted to use their judgement call on their prescribing behavior. Often, these attempts proved a failure and more drug dependency over the last two decades. Despite the fact that PDMP helped resolve some of the issues clinicians face in front of opioids' addicts, the majority of the participants have argued that reducing the volume of opioids prescriptions is somehow good, yet not where it needs to be. At this stage, clinicians have a major role in determining which patient is to receive the prescription and in what quantity, also, to familiarize themselves with the process. Today, the PDMP system utilization process had reached every physician nationwide and made he/her practice more geared toward treating the cause not the symptoms in this case. Therefore, clinicians attitude toward prescribing opioids is considered a manifestation toward considering alternative treatments that improve patients' life expectancy and physical stability.

CONCLUSIONS

This study reveals the positive impact of PDMP system on physicians' ability to manage and control the opioids' prescriptions, and revealing the problematic patients who are identified as addict who are struggling to stop using the drugs on their own, yet, have no power either to take proper actions to help the clinicians help them. That is where the challenge takes place. With time, clinicians hope to see higher percentage in the number of patients who are no longer dependent. Unfortunately, this battle still in its early stages. Therefore, we recommend future follow-up quantitative study, a year or two from the date of this study, on the outcomes of the PDMP system and its impact on the overall population health, healthcare cost reduction, and decrease of mortality rate.

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