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Philadelphia College of Osteopathic Medicine Graduate Program in Biomedical Sciences School of Health Sciences

A Proposal to Implement a Must-Use Mandate for

Prescription Drug Monitoring Programs in Philadelphia

A Capstone in Public Health by Anugraha Kutty Copyright 2020 Anugraha Kutty

Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Science in Biomedical Sciences, Public Health Concentration

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ABSTRACT

Over the past two decades, there has been a rapid increase in the number of drugrelated deaths in the United States as a result of the current opioid epidemic (Capper et al., 2018). In 2016, the number of deaths caused by drug overdoses in the United States was at least 63,000 (Ashburn, 2016). During the same year, Pennsylvania had the third highest percentage of drug overdose death rates in the country (Multiple cause of death 1999–2017, 2018). A division of drug abuse prevention policy present among 49 out of 50 states are programs known as Prescription Drug Monitoring Programs (PDMPs) (Weber, 2019). These programs are statewide electronic databases that track all controlled substance prescriptions. Although PDMPs were introduced to decrease the prescription rate and the amount of doctor shoppers in each state, only four states have a must-use mandate requiring practitioners to use PDMPs. All other states without a mustuse mandate significantly underutilize PDMPs-Pennsylvania being one state without a must-use mandate. The objective of this study is to evaluate the impact of PDMPs on drug-related deaths, prescription rates, doctor shoppers, and other trends related to the opioid epidemic in the United States. The results from the four states with must-use mandates, Ohio, Kentucky, Tennessee, and New York, suggest successful outcomes from PDMPs. Therefore, it is suggested that future directives in Pennsylvania and Philadelphia should use these data to implement a must-use mandate of their own to follow similar trends. A strong initiative taken towards initiating must-use mandates of PDMPs is necessary to reduce prescribing rates and slow the rapid rate of increase of drug-related deaths in the United States.

BACKGROUND

I. Background

The number of drug overdose deaths continues to rise in the United States. The CDC reports approximately 192 drug overdose deaths every day (Multiple cause of death 1999—2017, 2018). In 2017, overdose deaths involving opioids specifically accounted for nearly 68% of all drug overdose deaths. Additionally, the state that has the third highest rate of death because of drug overdose (44.3 per 100,000) is: Pennsylvania (Multiple cause of death 1999—2017, 2018). Philadelphia is the leading district in Pennsylvania for overdose deaths at 60 deaths per 100,000 deaths, which is greater than the state average (The Opioid Threat in Pennsylvania, 2018). Deaths by drug overdoses continue to follow a 4-fold increase which has occurred in Philadelphia in recent years (Capper et al., 2018). Although there has been a rise in implementation of health care policy and interventions to combat the opioid epidemic, further changes and initiatives are necessary to continue to decrease opioid prescribing rates.

II. Regulating Opioid Prescribing Rates

Other states, such as California, have implemented comprehensive programs which have significantly decreased opioid prescribing rates. For example, the Kaiser Permanente of Southern California group implemented a program to assess the necessity of prescribing opioid medications before prescribing the drug. Among the physicians following these guidelines, Kaiser Permanente reported a 30% reduction in prescribing opioids in high doses and a 95% reduction in prescribing brand name opioidacetaminophen products. These programs include monitoring the adherence to prescribing and dispensing policies, patient follow-up, and increased use of electronic health records. The underlying goal is to transform the treatment and outlook of chronic pain to reduce unnecessary prescriptions (Losby, Hyatt, Kanter, Baldwin, Matsuoka, 2017).

According to the CDC, the likelihood of long-term use of opioids increases based on the duration of the initial prescription (Shah, Hayes, Martin, 2017). Specifically, the chances of long-term use increases after three to five days of taking a prescription. Therefore, between 2015 and 2017, 33 states, including Pennsylvania, passed forms of legislation to regulate the opioid epidemic by limiting prescribing practices. Pennsylvania passed a bill in 2016 that limits first-time opioid prescriptions to seven days, which is the most common number of days among the 33 states (Shah, Hayes, Martin, 2017).

Another branch of prevention policy present among 49 out of 50 states are Prescription Drug Monitoring Programs (PDMPs) (Weber, 2019). These programs are statewide electronic databases that track all controlled substance prescriptions. These programs improve patient safety by allowing clinicians to identify patients who are receiving opioid prescriptions from numerous providers, calculate the total amount of opioids prescriber per day (in MME/day), and identify patients who are being prescribed other drugs that can increase risk of using opioids (Prescription drug monitoring programs (PDMPs)). Although the impact of the state-level PDMPs were mixed, states with more comprehensive monitoring resulted in larger reductions in overdoses compared to states with less comprehensive monitoring among Medicare beneficiaries (Weber, 2019; Moyo et al., 2017). Several states have recently enacted and modified their PDMPs which most probably contributed to the emerging data that suggest fewer patients receiving opioids with lower initial doses which result in a shorter duration of treatment of opioids (31, 44). Pennsylvania did not have an active PDMP until recently when legislation was passed in August 2016 (Ashburn, 2016). As of September 2019, Pennsylvania shares data from the PDMPs with 21 other states, military health systems and D.C. Interstate Sharing to provide a comprehensive background check of patients in need of opioids (Prescription drug monitoring program (PDMP), 2019).

The introduction of PDMPs has supporting evidence of decreased opioid prescription rates among the states and hospitals that are readily using them. They have been identified as a useful tool to reduce opioid prescription abuse. However, since PDMPs have recently been incorporated into health systems, they are being underutilized by providers because there are barriers to their use. Additionally, 25% of primary care physicians surveyed by Johns Hopkins University stated that they were not aware they had a PDMP (Rutkow, Turner, Lucas, Hwang, Caleb, Alexander, 2015). As suggested by the Johns Hopkins researchers, there are a few ways to strengthen PDMPs such as increasing legal mandates, investing in prescriber education, and enhancing ease of access to and use of the programs (Rutkow, Turner, Lucas, Hwang, Caleb, Alexander, 2015).

One form of legislation, which was mandated to increase the use of PDMPs, is a must-use mandate for PDMPs. Only four states have implemented must-use mandates: Ohio, Kentucky, Tennessee, and New York (Haffajee, Jena, & Weiner, 2015). This mandate requires the use of PDMPs statewide with penalties for underutilization. Therefore, every practitioner and pharmacist in the four states with must-use mandates must query the system before prescribing and opioid and report the prescription into the PDMP system within one business day of the prescription (Haffajee, Jena, & Weiner, 2015).

In recognition of the increasing success of reducing opioid prescription rates through the use of PDMPs, legislators should continue to strengthen these programs, especially in the city of Philadelphia, to reduce the high rate of overdose deaths. Additionally, the expansion of sharing PDMP data with more states could also result in a more comprehensive view of each patient. By advocating for increased use of PDMPs through legislation, the amount of overdose deaths in Philadelphia could potentially decrease. To address the advancement of PDMPs in the state of Pennsylvania, starting at the city council level will encourage state-level legislative change.

RESEARCH STRATEGIES

This capstone analyzes reported trends in data regarding prescription rates in states that have implemented a must-use mandate for PDMPs. Multiple studies which investigate the performance and success of PDMPs analyze all 49 states collectively instead of focusing on the states that mandatorily use PDMPs. By comparing the four states that have must-use mandates with the remaining 45 states which don't have a must-use mandate, the results become skewed. States with must-use mandates are required to produce an annual report with the statistics concerning trends related to the opioid epidemic. Therefore, in this investigation, the annual PDMP reports from the four states with must-use mandates will be studied.

A systematic literature review was conducted to determine the impact of implementing PDMPs. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRIMSA) guidelines were used to improve the quality and consistency of the identified reports and studies for this capstone paper. The following inclusion criteria were used to identify reports and studies related pertaining to this topic:

- 1. English-language studies performed in the United States between 2010 and 2020 through the "most recent" searching filter.
- 2. Individual state level reports of usability, utilization, and outcomes of PDMPs
- 3. Individual state level reports of opioid prescription rates
- 4. Must identify the use of PDMPs by the state in the report

Data related to the impact of trends related to opioid prescription rates were summarized and analyzed.

RESULTS

Out of all states investigated in this study, 49 out of 50 states have implemented the use of PDMPs. Out of the 49 states, only 4 states have must-use mandates for providers to actually utilize PDMPs in practice: Ohio, Kentucky, Tennessee, and New York. All other states allow voluntary reporting of prescriptions in PDMPs, including Pennsylvania. Pennsylvania is only required to query the system before prescribing an opioid (PDMP Annual Report 2016-2017, 2020). Compared to the states with a must-use mandate which are required to report prescriptions into the PDMP, Pennsylvania is not required to report prescriptions into the PDMP daily. Therefore, the statistics regarding the PDMP in Pennsylvania only report an increase in the number of queries since the PDMP has been implemented. Data concerning the effect on prescribing rates, doctor shoppers, and other trends associated with the opioid epidemic in Pennsylvania are not well known. This may be associated with the fact that Pennsylvania does not have a must-use mandate for PDMPs. The following results will describe the trends of opioid prescription rates and doctor shopping related to the opioid epidemic in the four states that have must-use mandates for PDMPs.

Ohio

Ohio developed a drug monitoring program specific to the state entitled the "Ohio Automated Rx Reporting System" (OARRS). This database serves as the only statewide electronic database which stores all controlled substance dispensing and personal furnishing information. According to the OARRS Annual Report, Ohio continues to advance in safe prescribing methods of opioids. Additionally, it indicates that the total number of opioid doses decreased from 793 million in 2012 to 415 million in 2019 and the total number of opioid prescriptions decreased by 5 million during the same period of time—these differences are a 48 percent and 40 percent decrease, respectively (Figures 1, 2). As seen in Figure 3, the average daily MED per instance of personal furnished opioids by Ohio prescribers has also decreased since 2010 (Ohio Automated Rx Reporting System 2019 Annual Report, 2019). As MED decreases, the less likely an adverse event occurs.

The overall mandate for PDMPs requires that doctor's query the program before prescribing opioids—again, the purpose is to avoid doctor shopping and reduce opioid prescription rates. The number of queries in OARRs increased from 1.78 million to over 240 million over the course of 9 years. Contrastingly, the number of reported doctor shoppers decreased 88 percent over the same 9-year period (Figures 7, 8) (Ohio Automated Rx Reporting System 2019 Annual Report, 2019).

Kentucky

Similar to Ohio, Kentucky also designed its own prescription monitoring program entitled "Kentucky All Schedule Prescription Electronic Reporting" otherwise known as KASPER. The CDC reported Kentucky as a success in reducing opioid prescriptions due to the mandatory use of KASPER and regulation of pain clinics across the state. The Kentucky Office of Drug Control Policy states that since Kentucky mandated the use of KASPER in 2012, there has been a 22% decrease in the number of opioid doses prescribed since 2011 (Figure 5) (Opioid Abuse in Kentucky, 2019). According to the 2019 KASPER Indicator Progress Report, the rate of Kentucky Multiple Provider Episodes for Prescription Opioids, otherwise known as doctor shopping, has steadily decreased since 2014. The percentage of Kentucky Patients Receiving more than an average daily dose of \geq 100 MMEs of Opioid Analgesics went from 39.39% in 2014 to 14.1% in 2018 (Akers, Quesinberry, & Bunn, 2019).

Tennessee

Tennessee also has its' own prescription drug monitoring program called the Tennessee Controlled Substance Monitoring Database (CSMD) which provides health care practitioners with a patient's prescription history. Mandatory registration in the CSMD started in 2013 but became more utilized in 2016 when data were required to be submitted every day (Tennessee Department of Health, 2020). The Tennessee Department of Health released the 2020 annual CSMD report which contained the following key findings:

- The number of prescriptions for opioids decreased by 38% since 2012.
- The average MME prescribed and dispensed to patients statewide decreased by 53% since 2012.
- The number of people prescribed more than 120 MME/day decreased by 52% since 2012.
- The number of potential doctor shoppers detected by the system decreased by 89% since 2011 (Figure 6).
- The number of CSMD searches and queries has increased by 603% since 2012 and continues to rise.
- The number of controlled substance prescriptions entered to the CSMD has decreased by 11% since 2013.
- On average, there was 1 search for every 1.3 prescriptions in Tennessee in 2019, compared to 1 search for every 12 prescriptions in 2011.

New York

New York state mandated the use of their Prescription Monitoring Program registry (PMP) in 2012, which requires any practitioner writing a prescription to report it in the system. The following trends have resulted:

- A 22% decreased in the rate of opioid prescriptions between 2015 and 2018.
- The number of patients who received opioids from 5 or more prescribers, at five or more pharmacies, otherwise known as doctor shoppers, decreased significantly from 8.7 per 100,00 in 2015 to 1.3 per 100,000 in 2018 (NYS Department of Health, 2019).
- Practitioners in New York wrote 37.8 opioid prescriptions per 100 persons in 2017, which was one of the lowest rates in the country for that year. The average rate of opioid prescriptions per 100 persons was 58.7 in the United States in 2017 (NYS Department of Health, 2019).

DISCUSSION

The data obtained from each state's reports indicate successful utilization of PDMPs in reducing opioid prescription rates. These data provide evidence that comprehensive use of PDMP mandates for practitioners increase PDMP use and influence opioid prescribing rate trends. Without the implementation of the must-access mandates in these states, it seems unlikely that these trends in opioid prescription rates and doctor shopping would have occurred in a similar manner. The start of opioid substance use disorder from prescription opioids is ongoing, however it can be reduced through increased implementation and regulation of how opioids are prescribed, when they are prescribed, and who they are prescribed to. These factors are accounted for through PDMPs.

Although Pennsylvania has a PDMP in place, it is not required for prescribers to check the PDMP before an initial opioid prescription and prescribers are not required to conduct subsequent interval checks after a prescription has been made. Through the aforementioned trends in the states that have implemented mandatory utilization of PDMPs, it seems necessary for a nationwide mandate to encourage similar trends in the remaining states, Pennsylvania being one of them. The demand for decreasing opioid prescription rates in Pennsylvania is high due to the ongoing placement of Pennsylvania as the third leading state in the country for the number of opioid deaths per year.

RECOMMENDATIONS FOR FUTURE STUDIES

The data described above provide evidence that mandating the use of PDMP by practitioners nationwide could contribute to an overall reduction in prescribing opioids and doctor shopping in each state. It is recommended that advocates for combating the opioid epidemic in Pennsylvania should work with health care professionals and associated stakeholders to gather and present the evidence needed to encourage policy change in the Pennsylvania General Assembly. The results of this investigation can be presented to various state level legislators to develop a must-use mandate for PDMPs in Pennsylvania. However, if it is possible to start at the city level, it is recommended to implement a must-use PDMP mandate in the city of Philadelphia. This city should adopt this mandate since it is reported as the district with the greatest number of opioid deaths in Pennsylvania.

PDMPs are useful systems for practitioners in making informed prescribing decisions in practice. It is necessary for other states to recognize the degree of operability and meaningful results that come from this tool. Therefore, it is critical to talk to legislators, government officials, local residents, and members of the health care community to inform them of the systematic benefit of using PDMPS to improve one aspect of the multifaceted opioid epidemic that Philadelphia is experiencing, along with the rest of the country.

Future studies should continue to collect data from other states that have mandates for PDMP use to statistically analyze the drastic statistical differences seen from PDMPs. Many of the studies that have similar comparisons fail to acknowledge the differences in states that have a must-access mandate and therefore the results are skewed. The United States are on the road to mandating PDMP usage nationwide in the future, however future studies can be a catalyst for this process.

Finally, future studies should investigate the number of practitioners and pharmacists aware of the value and results of using PDMPs. As of now, many providers are unaware and underutilize PDMPs which caused the need for the must-use mandates. By investigating these trends, future studies can combine this information with the trends of states that have must-use mandates to show how utilization increases after mandates are implemented. These data can be used when discussing with legislators to influence their view and understanding about the need for a new mandate.

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APPENDIX A

Relative Definitions

Opioids- A class of pain-relieving medications used to reduce the level of pain a person is experiencing. Prescription opioids are prescribed to people undergoing moderate to severe pain due to chronic pain or pain occurring after surgery or injury. The term "opioid" encompasses natural, synthetic, or semi-synthetic chemicals that have similar pain-relieving effects. These chemicals bind to opioid receptors throughout the body and decrease the amount of pain felt (Commonly Used Terms). Examples of opioids include:

Natural Opioids: Morphine and Codeine

Semi-synthetic Opioids: oxycodone, hydrocodone, hydromorphone, and oxymorphone

Synthetic Opioids: Methadone, Tramadol, and Fentanyl

Opioid Use Disorder (OUD)- According to the DSM-5, OUD is a problematic pattern of opioid use that causes significant impairment or distress. The diagnosis for OUD is dependent on a variety of factors such as: the amount of opioid intake, unsuccessful efforts to cut down or control opioid use, desire to use opioids, social or interpersonal problems caused by the effects of opioids, failure to maintain social, occupational, and recreational activities, recurrent use of opioids, and exhibiting tolerance of or withdrawal from opioids (Module 5: Assessing and addressing opioid use disorder (OUD)).

Opioid Epidemic or **Opioid Crisis**- The increased use of opioid drugs resulting in increased drug overdose deaths in the United States (Commonly Used Terms).

Medication-assisted treatment (MAT)- The combination of medication (such as methadone, buprenorphine, or naltrexone), counseling, and behavioral therapies used to treat opioid use disorder (Commonly Used Terms).

Illicit drugs- Drugs used for non-medical related reasons that are prohibited by law. Opioids such as heroin and illicitly manufactured fentanyl fall under this category (Commonly Used Terms).

Morphine Equivalent Dose (MED)- the total amount of opioid medications, converted to a common unit (milligrams of morphine), that a patient currently has access to based on the information reported by prescribers and pharmacists to OARRS. Morphine is known to be the standard for treatment of moderate to severe pain and use used a reference point (Ohio Automated Rx Reporting System 2019 Annual Report, 2019).

Personal Furnished- The distribution of drugs by a prescriber to the prescribers' patients for use outside the prescriber's practice setting (Ohio Automated Rx Reporting System 2019 Annual Report, 2019).

Doctor Shopper- An individual receiving a prescription for a controlled substance from five or more prescribers in one calendar month (Ohio Automated Rx Reporting System 2019 Annual Report, 2019).



APPENDIX B

Figure 1. Opioid Solid Doses Dispensed to Ohio Patients, by Year (Ohio Automated Rx Reporting System 2019 Annual Report, 2019).



Figure 2. Opioid Prescriptions Dispensed to Ohio Patients, by year (Ohio Automated Rx Reporting System 2019 Annual Report, 2019).



Figure 3. OARRS Queries, by year (Ohio Automated Rx Reporting System 2019 Annual Report, 2019).



Figure 4. Total Doctor Shoppers, by year (Ohio Automated Rx Reporting System 2019 Annual Report, 2019).



Figure 5. Annual Opioid Analgesic Doses as Reported to KASPER (Akers, Quesinberry, & Bunn, 2019).



Figure 6. Potential Doctor and Pharmacy Shoppers identified by CSMD (Tennessee Department of Health, 2020).