



POLICYMAKING IN THE DIGITAL AGE

Strengthening Prescription Drug Monitoring Mandates in the US

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INTRODUCTION

The number of individuals who have been dying due to opioid overdoses has been steadily increasing in the United States. From 1999 to 2015, the number of overdose deaths involving opioids nearly quadrupled, such that 91 Americans died each day in 2015 (CDC, 2016). The official statistics are not yet available, but provisional figures indicate that the rate of opioid overdose death has continued to increase through 2016 and 2017 (NVSS, 2017). As this policy brief will discuss, there is evidence that the opioid epidemic is linked to prescription opioids, and that high prescription rates may have partially driven the increase in overdose deaths. In response to this evidence, healthcare providers must examine the risk of addiction, overdose, and other adverse health outcomes for each patient and balance these risks with the potential pain relief benefits of prescribing opioids.

Relatively new digital technologies have created new ways to assess these risks and benefits, as well as new ways to identify prescribers and patients with problematic behaviour surrounding prescription opioids. Prescription drug monitoring programs (PDMPs) are state-wide databases that track prescribing behaviour for controlled substances at the individual patients and physicians level. This data can be accessed in real time by physicians, pharmacists, and other appropriate parties to help them provide the most appropriate care for patients as well as to help identify patients who seek opioids from multiple prescribers and even identify physicians that may prescribe excess opioids. PDMPs exist in all states except for Missouri, but

the specific legislation regulating their use varies from state to state. There are several best practices that all states should adopt to ensure that PDMPs are used effectively to positively impact health outcomes for patients. This paper focuses on mandatory consultation of PDMP data by prescribers before writing opioid prescriptions as a best practice in PDMP legislation. It includes a discussion regarding the evidence that mandatory consultations reduce the number of opioids that physicians prescribe, and thereby reduce overdose deaths. The paper then makes specific policy recommendations to improve state-level PDMPs by creating wider and more objective criteria for mandatory consultation.

THE PRESCRIPTION OPIOID EPIDEMIC: CONTEXT AND SCOPE

Scope of Opioid Epidemic

Since 2000, more than a half million people have died in the U.S. from drug overdoses (Rudd et al., 2016). The number of annual overdose deaths in the U.S. has now surpassed the number of HIV deaths at the peak of the AIDS epidemic in 1995, indicating the severity of the problem and the urgency to remedy it (Katz, 2017). The age-adjusted drug overdose death rate increased by 250 per cent from 1999 to 2015, from 6.1 per 100,000 in 1999 to 16.3 in 2015 (CDC, 2016). Opioids are a primary driver of this increase in the overall drug overdose death rate, and were involved in over 60 per cent of all overdoses in 2015 (Rudd et al., 2016). The opioid overdose death rate has increased by more than 350 per cent, from 2.9 per 100,000 in 1999 to 10.4 in 2015, although this is likely a conservative estimate since not all records of drug overdose deaths include specific drugs in the re-

port (CDC, 2016). Due to the severity of the issue, the Center for Disease Control and Prevention (CDC) has declared the opioid problem a national public health epidemic in the U.S.

This epidemic affects people across geographic and social boundaries. Past drug epidemics, especially the cocaine and crack epidemic of the 1980s, were associated with minority populations in urban areas. However, the opioid epidemic has been affecting more White communities in suburban and rural areas than past drug epidemics in America. The highest rates of prescription opioid overdose deaths are among those 24 to 54 years of age, and rates are higher in non-Hispanic Whites and American Indians or Alaskan Natives compared to non-Hispanic Blacks and Hispanics. Although men have historically had higher rates of prescription opioid overdose deaths than women, the gender gap is closing (Rudd et al., 2016).

What Evidence Tells Us about the Prescription Opioid Epidemic

There is mounting public recognition that opioid overdoses are a significant public health concern, and that liberal prescribing practices have contributed to the problem. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids (Rudd et al., 2016), and each day more than 1000 people are treated in emergency departments for not using prescription opioids as directed (CDC, 2016).

There is evidence to suggest that many patients that are prescribed opioids become dependent on them. Estimates of the risk of addiction among those that receive opioid prescriptions range from around 8 per cent in conservative studies, to upwards of 15 to 26 per cent in studies that expand the definition of addiction to include misuse and addiction-related behaviours (Volkow and McLellan, 2016). In a study of patient records from the IMS Lifeline+ database,¹ approximately 6 per cent of those that received

1. The study drew a random 10% sample of patient records from the IMS Lifeline+ database from 2006–2015. This database includes commercial health plan information from a large number of managed care plans and is representative of the U.S. commercially insured population (Shah et al., 2017).

an opioid prescription of at least one day still used prescription opioids one year later. This risk of continued use was higher among those that received longer initial prescriptions. Among a subset of the population that received an initial prescription of more than 8 days (70 per cent of the study population), the risk of continued use in one year was 13.5 per cent; and for the 7.3 per cent of the population that received initial prescriptions of more than 30 days, the risk of continued use in one year reached almost 30 per cent (Shah et al., 2017).

Although correlation does not prove causation, it is also informative to look at how opioid sales have increased during a period when opioid overdose deaths were also on the rise. The number of deaths from opioid overdoses quadrupled between 1999 and 2014 in the U.S., mirroring the increase in prescriptions for opioids (Rudd et al., 2016).² This increase in prescriptions occurred despite there being insufficient evidence to support that opioids are the most effective way of treating chronic, non-cancer pain. Multiple federal agencies such as the CDC and the Food and Drug Administration (FDA) have amended their guidelines for prescription opioids in response to this lack of data, and no longer endorse prescribing opioids as the best way to treat chronic non-cancer pain (Dowell et al., 2016).

2. Recently, there has been media attention regarding how pharmaceutical manufacturers systematically misrepresented the risk of addiction associated with opioids, and targeted physicians that prescribed most liberally in their marketing efforts (See Semuels, 2017).

POLICY ALTERNATIVES TO ADDRESS THE PRESCRIPTION OPIOID EPIDEMIC

Public Health Framework

It is useful to refer to a public health framework of primary, secondary, and tertiary responses as a way to classify different policy solutions to the opioid epidemic. Primary strategies in public health attempt to prevent exposure to risk factors that cause adverse health outcomes. For example, in the opioid epidemic this may include strategies to reduce the number of

prescriptions by encouraging physicians to prescribe more conservatively. Secondary strategies in public health look to screen patients for health issues before it causes serious harm. In the opioid epidemic, this means identifying patients with aberrant use behaviour before they experience serious health effects such as an overdose event. Lastly, tertiary strategies in public health involve therapeutic and rehabilitative measures once a diagnosis is firmly established (Kolodny et al., 2015). In the opioid epidemic, tertiary strategies include medically assisted treatment (MAT) for addiction, as well as increasing access to naloxone, a medication that reverses the effects of opioid overdoses.

Primary, secondary, and tertiary strategies can all be effective in reducing the harms associated with the opioid epidemic.³ However, the policy recommendation below is based on the assumption that primary strategies do more to get to the root cause of the prescription opioid epidemic; while tertiary strategies, although important, only treat individual patients who develop substance use disorders; and hence do not undertake systemic changes that would result in less people becoming addicted in the first place.

What are PDMPs?

PDMPs are state-level databases that track the prescription and dispensation of controlled substances, or drugs that have the potential for abuse. Although legislation regulating how often data must be put into the system varies from state to state, most states require that PDMP data is input either every day or within a week. This data can then be accessed via computer by prescribers, dispensers, and regulatory boards, in addition to other parties such as drug courts and medical examiners depending on the state. Some state PDMPs proactively analyse data to search for suspicious prescription patterns, such as providers or dispensers

3. See Wemeling, 2010 for evidence on the effectiveness of increasing access to naloxone in reducing deaths in the event of an overdose; Kolodny et al., 2015 for a discussion on the effectiveness of MAT in decreasing the risk of overdose, risk of relapse, and risk of overdose event during relapse compared to traditional treatment; and Nosyk et al., 2013 for cost-effectiveness analysis of MAT

that are responsible for the prescription and distribution unexpectedly large amounts of opioids and other controlled substances compared to other facilities. These proactive reports can then be passed along to appropriate parties such as law enforcement, professional licensing bodies, or the prescriber or dispenser depending on the state.⁴ PDMPs do several things. Firstly, having access to data about a patient's lifetime prescription history may help inform healthcare professionals of appropriate treatment options and protect patients from harms caused by over-prescription. Additionally, PDMPs can help identify doctor-shoppers, or patients that seek prescriptions from multiple prescribers either for their own use or for sale on the illegal market. Lastly, it can help identify prescribers with odd prescription patterns, such as those in "pill mills".⁵

4. See Prescription Drug Abuse Policy System for information about each state's policies and regulations that govern the use of PDMPs.

5. A pill mill refers to a doctor, clinic, or pharmacy that prescribe and dispense narcotics without a medical justification. These illegal operations flood communities with dangerous prescription drugs in order to make a profit.

Evidence for Prescription Drug Monitoring Programs

Evidence indicates that establishing a state-wide PDMP is associated with lower prescription rates for opioids. A study from 2001 to 2010 across 24 states found that PDMP implementation is associated with a reduction in the probability of being prescribed an opioid for pain from 5.5 per cent to 3.7 per cent. This is more than a 30 per cent reduction in the rate of prescription for opioids, which was maintained in the second and third year after implementation (Bao et al., 2016). Similarly, in a smaller study of authorized PDMP users in Rhode Island and Connecticut, results indicated that those that used PDMPs were more likely to respond with clinical measures such as referral to other healthcare providers, screening for drug abuse, and revisiting pain and treatment agreements, as compared to non-users of the PDMP, who were more likely to respond with either inaction or by contacting law enforcement (Green et al., 2012).

Along with decreasing the number of prescriptions, there is also evidence that PDMPs are associated with mitigated opioid abuse and misuse trends over time. A study of RADARS Poison Center and Opioid Treatment data from 2003 to 2009 (when PDMPs were still being established in most states) compares outcomes in states with PDMPs to outcomes in states that had not yet established a state-wide database, and finds that PDMPs were associated with slower growth in misuse and abuse trends. States without PDMPs saw an average of 1.9 per cent growth per quarter in Poison Center's opioid intentional exposures, while states with PDMPs saw an average of only 0.2 per cent growth. Similarly, opioid treatment admissions increased 4.9 per cent per quarter in states without PDMPs, and only 2.6 per cent in states with PDMPs (Reifler et al., 2012).

Although PDMPs in general show promising results, it is important to identify specific best practices that increase the positive impact that PDMPs have in healthcare. The following section breaks down identified best practices and provides evidence that mandatory consultation of PDMP data by prescribers' helps improve outcomes, as compared to PDMPs without strong mandatory consultation provisions.

POLICY SUGGESTION: ADOPTING BEST PRACTICES IN PDMP MANDATES

Public Health Framework

The American Pharmacists Association (APA) and the CDC suggest the following best practices in state PDMPs (American Pharmacists Association, 2014; What States Need to Know about PDMPs, 2016):

- ▶ universal use mandates;
- ▶ streamlining the process to register as a user;
- ▶ allowing delegates to access data on behalf of physicians;

- ▶ proactive reports to users to protect patients at high risk and identify inappropriate prescribing trends;
- ▶ real-time data;
- ▶ data-sharing across states;
- ▶ making active efforts to integrate PDMPs into clinical practice.

Evidence for the Effectiveness of Universal Use Mandates

Of these best practices, universal mandates have particular promise in maximizing the benefits of state-wide PDMPs. PDMP data is only useful when it is utilized, but without mandates that prescribers actually consult the data, most prescribers do not routinely check PDMP data unless they suspect misuse (Kolodny et al., 2015; Rutkow et al., 2015; Young et al., 2017). Studies show that state-level mandates are successful in increasing the number of prescribers that check PDMP data before prescribing, and are successful in influencing prescribing behaviour. A study that compared data from 38 states found that mandatory PDMP review along with pain clinic laws⁶ were significantly associated with decreased prescription of opioids and reduced prescription opioid overdose death rates; compared with states with only pain clinic laws or with no legislation in place. In these states, mandatory PDMP review laws and pain clinic laws reduced both the amount of opioids prescribed by 8 per cent and prescription opioid overdose death rates by 12 per cent (Dowell et al., 2016). This evidence supports the idea that more states should pass comprehensive PDMP mandates.

⁶ Pain clinic laws regulate the ownership, operation, and practice of clinics providing pain management services where practitioners prescribe opioids or other controlled substances to a large proportion of patients.

Although nearly all states have mandates in some form, they vary in terms of their strength and criteria for mandatory query. The PDMP Center of Excellence at Brandeis University breaks

down four different types of mandates, from most to least comprehensive (2016):

- ▶ States with the most comprehensive mandates require that prescribers consult the state-wide PDMP when initially prescribing any opioid or benzodiazepines⁷, with subsequent checks at three-month intervals should the prescriptions continue.
- ▶ States with mostly comprehensive mandates may not require initial checks for all opioids and benzodiazepines, and the requirements for subsequent queries may be at intervals greater than three months.
- ▶ States with less comprehensive mandates have categorical requirements rather than a universal mandate. Some require query for non-cancer chronic pain prescriptions only or for prescriptions for more than a certain length of time, such as 7 days.
- ▶ States with the least comprehensive mandates only require consultation based on subjective criteria, such as the prescriber's judgement of possible misuse. Mandates that only apply to certain settings such as pain clinics or opioid treatment programs also fall into this category.

7. Benzodiazepines are a class of anti-anxiety drugs that also have a high potential for abuse and overdose. Although opioids are the focus of this brief, PDMP mandates also apply to benzodiazepines.

Experience in a Model State: New York

New York is consistently cited as a model PDMP (Dowell et al., 2016; PDMP Center of Excellence at Brandeis University, 2016; Haffajee et al., 2015). The experience in this early implementer state provides evidence of the efficacy of mandated use of PDMPs and can inform legislative choices in other states.

New York first allowed authorized users to access PDMP data in 2010. In 2012, the state passed new legislation (I-STOP – Internet System for Tracking Over-Prescribing) that mandated that providers consult PDMP data before prescribing opioids, which

8. The United States began to classify drugs into schedules in 1970, when the FDA released the controlled Substance Act. A drug's schedule depends on its accepted medical use and the drug's potential for abuse. Schedule I drugs have high potential for abuse and no accepted medical use, Schedules II-IV have potential for abuse and accepted medical use, and Schedule V drugs have the least potential for abuse.

went into effect in August 2013. As part of New York's Public Health Law, practitioners must consult PDMPs when prescribing or dispensing controlled substances in Schedules II to IV⁸ with limited exceptions such as prescriptions for a supply of less than five days and those in hospice care. Should a provider fail to comply with this mandate, they can be found guilty of misdemeanour, which is punishable by up to a year's sentence or a fine not exceeding ten thousand dollars, or both.

Before implementing this mandate, New York's online PDMP had 3,087 users who averaged about 11,000 reports requested per month. Six months after the mandate was implemented, active users reached 67,779, who averaged about 42,300 requests per day (PDMP Center for Excellence, 2016). A year after implementation, there were notable differences in prescribing behaviour. The number of opioid prescriptions had decreased by 9.5 per cent, along with the number of individual patients with prescriptions. The number of individuals identified as possible 'doctor shoppers' - those that receive more than five prescriptions from five different prescribers in a three-month period - decreased by 82 per cent in the first two years. Additionally, prescriptions for buprenorphine increased by 14.6 per cent. Buprenorphine is an opioid partial agonist, which means that it produces some of the same effects as opioids such as euphoria and respiratory depression, but at a weaker level. Unlike a true opioid, the effects of buprenorphine level off at higher doses, which is referred to as a "ceiling effect." This effect reduces the drug's potential for misuse, dependency, and abuse, which in turn decreases the amount of harmful side effects in users. Buprenorphine is prescribed to people who suffer from opioid abuse disorder as a way to manage addiction, so the increase in buprenorphine prescriptions after New York implemented mandatory consultation of PDMPs indicates that more patients who abused opioids gained access to medically assisted treatment after the mandate was implemented

(PDMP Center of Excellence at Brandeis University, 2016; Haf-fajee et al., 2015).

CHALLENGES TO IMPLEMENTATION

Policy Suggestion for States: More Comprehensive Mandates for PDMP Consultation

Based on the demonstrated efficacy of PDMP mandates, other states should strengthen the language of their mandates in order to make the criteria for mandatory consultation wider and more objective. In particular, states that have not done so should aim to emulate the following measures from New York's PDMP legislation: mandatory consultation by prescribers every three months after initial prescription with certain exemptions for emergency care and hospice settings; punitive measures for prescribers and dispensers that fail to comply with mandatory consultation; and training for physician and pharmacists to provide them with adequate information to comply to this mandate.

PDMPs have already been implemented in forty-nine states, and data regarding the prescription history of patients and prescribers is already being recorded. The only cost associated with this policy suggestion is the time that it would take for healthcare providers to access PDMP data before prescribing an opioid.

Challenges with Key Stakeholder: Medical Providers

Medical providers are a key stakeholder in healthcare and PDMP legislation. The policy recommendation suggested above would mandate that they consult PDMP data before prescribing any opioid, which takes time and effort from them. This will especially affect providers that treat pain often, such as those in

pain medicine, surgery, and physical medicine specialties. Additionally, it will affect primary care providers, who account for about half of all opioid prescriptions and have more intense patient interaction than other providers (CDC, 2016).

Some physicians have opposed universal mandates based on arguments that they are a burden to use and negatively impact patient care (Haffajee et al., 2015). They argue that the time it takes to consult PDMP data takes away from valuable patient time, which can be used more effectively if the provider did not have to take time out of the visit to open the PDMP on the computer, search for the patient, and read the patient's prescription history. Surveys have identified more specific complaints regarding PDMPs including that they are time-consuming to use, the way the data is presented is difficult to understand, and there are barriers to access the data in busy work environments (Rutkow et al., 2015; Young et al., 2017). If states pass legislation mandating that prescribers consult PDMPs, measures should be taken so as to minimize the burden on prescribers and reduce the interruption to their practice that mandates impose. For example, adequate training for providers can help ease difficulties in use, which would ensure that providers do not face undue obstacles to query the system quickly and efficiently. Additionally, authorized third parties may be permitted to query the system rather than physicians. This would allow physicians to request that physicians' assistants or registered nurses look up a patient's PDMP data, and would allow the physician to continue their visit uninterrupted, addressing other pressing health issues while waiting for PDMP data to be collected by other office staff.

Responsibility of Providers to Balance Risks and Benefits of Opioids

Healthcare professionals have a responsibility to protect their patient's health and wellbeing. Professional organizations and governmental agencies have published their own standards surrounding this responsibility as it relates to the opioid epidemic. For example, in a report aimed towards primary care providers, the CDC urges that physicians, "Do no harm. Long-term opioid use has uncertain benefits but known, serious risks." The report suggests that providers consult PDMP databases for certain risk factors which are strong predictors of prescription opioid overdose⁹ before prescribing an opioid to any individual patient in order to more accurately assess the risks and benefits of prescription (CDC, 2017). For instance, if a patient was in need of pain relief, but PDMP data indicated that they had already been prescribed opioids by 4 or more physicians in the past, the provider may choose to prescribe a pain medication with less potential for abuse in response to this information.

Similarly, the APA outlines prescribers' responsibilities regarding safe opiate use: balancing the legitimate need for pain management and the risks associated with prescription opioids; assessing each patient before prescription; responsibly handling controlled substances and adhering to federal and state regulations; and enacting strategies to prevent abuse and diversion into the illegal market (American Pharmacists Association, 2014). Consulting PDMPs can help physicians fulfill these responsibilities by providing them with more complete information about prescription histories, which can lead to better medical judgment. Also, PDMPs can facilitate identification of individuals responsible for diversion of opioids to the illegal market. The APA has expressed public support for PDMPs, along with the American Medical Association and the Federation of State Medical Boards.

⁹. Patients with one or more risk factors (4 or more prescribers, 4 or more pharmacies, or dosage of more than 100 morphine milligram equivalents per day) accounted for 55% of all overdose deaths (CDC, 2017)

CONCLUSION: RESPONSIBLE POLICIES IN THE DIGITAL AGE

The digital infrastructure supporting prescription drug monitoring programs is already in place in nearly all states in the U.S., and data is already being collected regarding prescription behaviour for individual patients and prescribers. Targeted policies that increase the use of PDMP data can help ensure that the resources that have already been used to support the implementation of PDMPs have greater positive impact on health outcomes. Evidence suggests that creating a wider and a more objective criterion for mandatory prescriber consultation of PDMP data can help influence prescribing behaviour and decrease opioid overdoses, as it did in New York. These strong mandates are a low-cost solution since they put technology that already exists to better use. This framework of putting existing digital technologies to new, more evidence-based uses can help inform not only PDMP legislation, but also all classes of cost-effective, responsible policies in the digital age.

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