Public Health Policy

and

Prescription Drug Monitoring Program Mandates

By

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Abstract

The abuse of, addiction to, and overdose from prescription opioid pain medications has become a leading public health concern in the United States. Overdose has become the leading cause of unintentional death and opioid pain medications are the leading cause of overdose. States are developing policy and passing legislation to address the opioid issue. Forty-nine states and the District of Columbia have passed legislation to develop prescription drug monitoring programs (PDMPs) to track opioid dispensing. These programs have the potential to improve public health through data collection and analysis as well as through use by prescribers as a tool to better understand the prescription history of their patients.

Unfortunately, as these are relatively new programs, it is unclear how they may best be utilized. Many states are passing legislation that prescribers must check the PDMP in certain situations prior to prescribing controlled substances. Three states – Kentucky, New York, and Tennessee – have had comprehensive mandates for over three years and it is possible to evaluate these programs and their impact on the opioid problem in these states. All three states have reported that the mandates have reduced “doctor shopping”. Doctor shopping is defined as a patient going to multiple prescribers and multiple pharmacies to obtain excessive amounts of opioid pain medications.

This paper examines the PDMP prescriber mandates in Kentucky, New York, and Tennessee to evaluate their cost and benefit. The conclusion is that there is no evidence that mandates have a significant effect on overdose deaths, prescribing of opioids, or admissions for treatment of opioid use disorder. Their use comes at a very high cost that may have a negative impact on public health by reducing the availability of medical providers.
Introduction

The United States is in the middle of an opioid crisis. The prescribing, use and abuse of opioid pain medications has increased dramatically over the past twenty years. Overdose deaths have become the leading cause of unintentional death, surpassing motor vehicle crashes in 2008 (Warner, Hui Chen, Makuc, Anderson, & Miniño, 2011).

To address this, states have begun legislating programs and policies to improve the prescribing of opioids and reduce addiction, overdose and death. Forty-nine states have created prescription drug monitoring programs (PDMPs) (PDMP TTAC, 2016c). These programs record controlled substances dispensed by pharmacies and can be accessed by prescribers to get a better understanding of their patients’ prescription record. There is concern that underutilization of these programs will result in inappropriate prescribing leading to increase use of opioids and opioid overdose death (Alexander, Frattaroli, & Gielen, 2015). Many states have responded by creating laws making it mandatory for prescribers to check the state PDMP prior to prescribing controlled substances.

Kentucky, New York, and Tennessee have had programs that require PDMP checks in most situations for over three years. Reports of outcomes from these states have all been positive (Freeman, Goodin, Troske, & Talbert, 2015; NYSDOH, 2016; PDMP COE, 2016; TDOH, 2016) and several organizations have recommended that the optimal use of a PDMP includes legislated mandatory checks by prescribers (CDC, 2016; National Governors Association, 2016; PDMP TTAC, 2016b)(Alexander et al., 2015).

As the entire country has experienced decreased prescribing of opioids over the past several years and states have enacted multiple legislative efforts at the same time as mandating
prescriber checks, it is difficult to know if mandates in and of themselves are effective in reducing drug use and overdose.

This report will make a comprehensive evaluation of the benefits and extra-monetary costs of mandating prescriber checks of the PDMP.

**History of opioids**

Humankind has used opium and its analogs for thousands of years for both good and bad. The Sumerians documented the cultivation and utilization of opium over five thousand years ago. Hippocrates wrote of using opium to treat both pain and depression (Benyamin et al., 2008). In the 1800s, England shipped large amounts of opium to China resulting in a crisis of addiction and leading to the Opium Wars. The United States began controlling the sale of opioids in 1914 to address the national problem with opium, morphine, and heroin (Booth, 1996). America is currently experiencing another epidemic of opioid use and abuse that has resulted in the deaths of hundreds of thousands as well as the destruction of countless lives, families, and communities.

Opioid medications, by definition, are medications that act on the opioid receptor and have characteristics similar to opium. Opium is a natural product of a specific breed of poppy – *Papaver somniferum*. Opium contains 80% morphine, 15% codeine, and 5% thebaine.

The problem of opioid use, abuse and overdose is complex and the medical profession, local communities, states, and the federal government all have an important role to play to make sure that these medications are used appropriately.

Opioids were widely available in our country from the mid-1800s through the early 1900s until the passage of the Harrison Narcotics Tax Act of 1914. Through this act all opioid
medications were taxed and controlled making it much more difficult to obtain opium, morphine, and heroin that had previously been available over the counter (Booth, 1996).

The medical community recently has become much more conscious of the dangers of opioid medications. Opioids through the mid-1900s were only for the most severe pain and usually in a hospital setting. In a 1980 letter to the editor in the New England Journal of Medicine, Drs. Porter and Jick reported on an evaluation of over 11,000 patients in the hospital finding that use of opioids led to only four developing signs of addiction (Porter & Jick, 1980). In 1986, a case report of 38 patients by Portenoy and Foley claimed that addiction was rare in those treated for chronic pain (Portenoy & Foley, 1986). Following that, opioid prescribing increased every year (Paulozzi & Baldwin, 2012), fueled by a combination of physicians’ desire to treat their patients more compassionately, unethical marketing by the pharmaceutical industry (Van Zee, 2009), and the positive reinforcement of consuming opioids (Polunina & Bryun, 2013). Concomitantly with opioid prescribing, there was an increase in opioid use disorder and opioid overdose deaths. The CDC has shown that the increase in addiction and death is a direct result of the increase in prescribing of opioids (Paulozzi, Jones, Mack, & Rudd, 2011).

Unintentional death is the fourth leading cause of death in the United States behind cancer, heart disease, and lower respiratory disease. Overdose is now the leading cause of unintentional death, surpassing motor vehicle crashes in 2008. Most overdoses are caused by opioid pain medications.

**Opioid Use Disorder**

According to the American Society of Addiction Medicine: “Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry” (ASAM, 2011). Addiction to
opioids is called Opioid Use Disorder (OUD). OUD can result from prolonged exposure to opioid medications or heroin and is more common in those with risk factors. Because the use of opioids results in permanent changes to the brain, OUD is truly a disease of the brain and not a “moral failing” as many believe (Murthy, 2016).

Prolonged use of prescription opioids - either by prescription or illicitly - leads to changes in the brain that initially result in increased dopamine secretion but later result in suppression of the opioid receptors, decreased dopamine secretion, and neuroplastic changes. These neuroplastic changes result in changes in neuronal dendrites and neuronal connections as well as changes in neurotransmitters (Dacher & Nugent, 2011). Because of this, it is common for those prescribed chronic opioids for chronic pain to develop an opioid use disorder. It is believed that as many as 50% of those on chronic opioid therapy (COT) may develop OUD (Martell et al., 2007).

Substance use disorder is also commonly called addiction. This is characterized by abnormal behavior in an effort to repeat reinforcing behavior despite negative consequences (APA, 2013). When this happens, those addicted to opioids may begin exhibiting unusual behaviors including buying opioids from other people or going to multiple doctors to obtain their medications. Seeing multiple providers to obtain a controlled substance is commonly known as "doctor shopping". Doctor shopping does result in higher consumption of opioids leading to an increased risk of overdose and death.

**Prescription Drug Monitoring Programs**

**History**

Prescription drug monitoring programs are state programs that record the dispensing of controlled substances. New York State began the first PDMP almost 100 years ago in 1918. This primarily was to monitor the use of illegal substances including heroin and cocaine. California
currently has the longest continuously operating program which began in 1939. Up until the last 15 years, PDMPs were primarily used for law enforcement purposes. PDMPs have multiple functions and yet at the same time, their primary goal is often unclear. A recent survey of PDMP legislation revealed that only 25 (out of 49) states name a purpose (or purposes) for the PDMP. Of those, 60% mentioned that the purpose was to “reduce misuse or inappropriate use of prescription medicines”. No state legislation mentions that the purpose of the PDMP is to reduce or prevent opioid overdose. Forty percent of states mention a law enforcement purpose. Only 16% mention that one purpose is “to identify patients in need of treatment or counseling” (Davis, Johnston, & Pierce, 2015).

Most would agree that a primary utility of a PDMP is as a tool enabling prescribers to provide better care to their patients. The question remains as to how we measure better care. What are the outcomes that we should measure to determine their effectiveness? There are several possibilities:

- Reduce overdose deaths.
- Reduce the inappropriate or dangerous prescribing of controlled substances.
- Identify people who are addicted to opioids and refer them for treatment.
- Prevent addiction by identifying those who may be taking excessive amounts of opioids but are not yet addicted.
- Identify individuals who are seeing more than one doctor to get controlled substances illicitly. These individuals are commonly called “doctor shoppers”.
- Identify prescribers who are prescribing excessive numbers of opioids.

With these potential uses in mind, every state except Missouri has developed a PDMP. Some states are just beginning data collection but other states have been using their PDMP for years
and are working in improving functionality of the PDMP. These programs appear to have great potential but we have only limited data on outcomes. Kentucky, Tennessee, and New York are three of the older and more established programs and they all have data showing that mandating universal use of these databases can reduce doctor shopping. However, whether reducing doctor shopping is an appropriate surrogate marker for improving public health and safety is yet to be determined.

**Who are we protecting?**

Nearly 19,000 people died of opioid overdose in 2014 (CDC, 2015). The combination of opioids with other substances – primarily benzodiazepines and alcohol – make them particularly deadly. Most experts believe that opioids and benzodiazepines should never be prescribed concurrently (Dowell, Haegerich, & Chou, 2016).

Of those who die from an overdose, there are three types of individuals:

- Some are taking their medications as prescribed. Studies have shown that the higher the dose of opioid, the more likely to die from an overdose.
- Some others may be getting medications innocently from more than one doctor. For example, they may be getting opioids from one doctor who is treating their pain and a benzodiazepine from another doctor treating their anxiety. While these medications are dangerous when taken together, the prescribing doctors may be unaware of the other prescription while the patient is unaware that the combination is so dangerous.
- The final group is those individuals who are taking opioids illicitly. They are almost always addicted. The DSM5 says that the diagnosis of addiction “is based on a pathological pattern of behaviors related to use of the substance” (APA, 2013 pg 483). If addicted to
opioids, the risk of overdose death is 1% per year. People also die when using opioids recreationally before addiction develops, although this is less likely.

Reducing doctor shopping is usually seen as a key goal (and a measurable one) for PDMPs. It is generally accepted that most doctor shoppers are individuals who are addicted to the controlled substance and are seeing multiple providers to supply their habit. (See Figure 1 below)

It is unclear what percentage of the opioids prescribed are given to doctor shoppers. It is likely a very small percentage. A recent study looking at doctor shopping estimated that about 0.7% of individuals who receive an opioid prescription are doctor shoppers. However, that 0.7% received about 4% of the opioids prescribed (McDonald & Carlson, 2013).

What is the ultimate outcome of preventing doctor shopping? Does it save lives? For those who have the disease of addiction, does it improve their survival or worsen it? Is there any data that can provide an answer to that? Most people with addiction need professional help to control the disease. Like diabetes, it is a disease that can seldom be controlled without professional guidance and medication. Unfortunately, research has shown that addiction treatment providers are in short supply (Jones, Campopiano, Baldwin, & McCance-Katz, 2015). Access to addiction treatment is often limited or unaffordable. If an individual with the disease of addiction has their supply cut off by a doctor who stops prescribing and has no access to treatment, they will turn to buying pills or heroin “on the street”.

The marked increase in the availability of heroin over the last several years has drastically changed the model of illicit opioid use in the United States. Ten years ago heroin was only available in large cities and urban markets. Today, because of the business model of Mexican drug cartels, heroin is ubiquitous in all areas of our country and in most locations is cheaper and easier to purchase than opioid pain medications (Quinones, 2015). Five years ago, the CDC
concluded that the number of opioid overdoses is directly related to the number of opioids prescribed (Paulozzi et al., 2011). With the widespread availability of heroin that is likely no longer the case. According to the National Survey on Drug Use and Health (NSDUH), 4 out of 5 current heroin users report that their opioid use began with prescription opioids (Muhuri, Gfroerer, & Davies, 2013).

**Figure 1. Stages in the process of addiction and where PDMP is most helpful (⭐)**

PDMP functionality

Every state (except Missouri) and the District of Columbia has their own PDMP and all work differently thereby making general conclusions about their utility impossible. In many states, it is typical for only about 30% of physicians to be registered to use the PDMP and only about ½ of those access the system on a regular basis (Haffajee, Jena, & Weiner, 2015). Some states have legislatively mandated that prescribers access the PDMP prior to prescribing in an effort to increase utilization.

While increasing use of the PDMP intuitively appears to be a good idea, there are several problems with the use of the PDMP to improve health.

- Prescribers receive no training in the use of the PDMP or the interpretation of the findings.

  In some patients, the results will clearly show that they have received very few or no controlled substances. This will not necessarily mean it is safe to give this patient an
opioid prescription as there are many other factors that may make it unsafe including certain medical conditions and risk of addiction. It will, however, easily show that this individual is not doctor shopping. This is the great majority of patients. A recent survey of doctors in New York found that 60% of them identified suspicious results in <2% of their searches (Blum, Nelson, & Hoffman, 2016).

- Other reports may clearly show that the patient is getting prescriptions from many prescribers and is going to multiple pharmacies. In this case the interpretation is also clear.

- However, some results are not so straightforward. Some results may show minor variations in refill frequency or number of doctors that make it difficult to determine if this person is doctor shopping or on a dangerous combination of medications. There are no set rules for determining aberrant behavior and even experts cannot determine strict criteria (Sansone & Sansone, 2012).

- The use of a PDMP will impact office work-flow and consume valuable prescriber and staff time. An Op-ed in the NEJM in 2012 listed the ideal characteristics of a PDMP. It also referenced a survey of prescribers on why they do not reference the PDMP. Time constraints was the primary reason cited by 73% of prescribers followed by the belief that it would not change care cited by 39% of providers. (Perrone & Nelson, 2012)

**Measuring outcomes.**

Identification of doctor shoppers is often cited as an advantage and is a measured outcome of PDMPs. If prescribers can identify “doctor shoppers”, how effective is that at improving the public health? What are the possible outcomes? Do we know what happens after that? There are several possibilities:
1. The patient admits that they have the disease of addiction and the doctor can provide that treatment or refer to someone who does.

2. The patient admits that they have the disease of addiction and the physician does not refer them but tells them to get treatment.

3. The doctor does not discuss addiction but simply stops prescribing any more controlled substances.

4. The provider “fires” the patient, discharging them from the practice.

A successful outcome will result only if the patient gets treatment for their OUD. This is most likely with scenario 1. It is less likely with scenario 2. It is highly unlikely with scenario 3 or 4. Unfortunately, scenario 1 is the least likely as few doctors treat opioid use disorder and many do not know where to refer them. A recent national survey of 200 primary care doctors found that if doctors discovered their patients were doctor shopping, only 5% would treat their addiction in their own practice and only 38% would refer to treatment leaving over 50% without help for their life-threatening disease (Teater, 2016). Another recent study looking at actions taken after doctors were notified that their patients were doctor shopping found that out of 126 patients, only three were screened for a substance use disorder and none were referred for treatment of a substance use disorder (Thomas et al., 2014).

The only benefit of identification of doctor shoppers is if they stop their drug use and get into treatment. We know that this seldom happens. Because opioid use disorder is seldom successfully treated without the use of methadone or buprenorphine, these medications must be readily available to those who need treatment (American Society of Addiction Medicine, 2015). If the treatment is not available or if the individual does not want treatment, then the only alternative is to find other opioid drugs. Because cost and availability are major drivers for the
choice of opioid, many may turn to heroin which is now cheaper and more available than many of the prescribed opioids (Cicero, Ellis, & Surratt, 2012).

Reducing opioid prescribing may be a helpful outcome that is measurable. Because of the natural history of addiction, reducing the supply of opioid pain medications to those who are already addicted may lead to a transition to heroin use (Carlson, Nahhas, Martins, & Daniulaityte, 2016). However, if reduced prescribing occurs in those who are not addicted then there may be a reduction in development of opioid use disorder. Opioids prescribed to those who are not addicted significantly increases the risk of addiction (Edlund et al., 2014; Miech, Johnston, O’Malley, Keyes, & Heard, 2015; Odgers et al., 2008).

One goal of PDMPs may be to identify those with addiction and to get them into addiction treatment. If a PDMP is successful in this, there would be an increase in those entering treatment for OUD. The number of those entering treatment would be affected by the availability, accessibility, and affordability. If individuals have difficulty entering treatment, then this measure may see little change.

**Effectiveness of PDMPs in general**

Several studies have shown that the implementation of a PDMP by a state may improve opioid prescribing and result in better outcomes (Rutkow et al., 2015). A recent study by Patrick et al looked at opioid overdose mortality rates in states with a PDMP. They compared death rates prior to implementation of the PDMP to death rates after. They found that implementation of a PDMP appeared to reduce the expected death rate from opioid overdose by about 1 person per 100,000 each year (Patrick, Fry, Jones, & Buntin, 2016).
State Models

Each PDMP is developed and operated by the state or district in which it resides. Because of that, each PDMP is different in how it functions. Some PDMPs are more comprehensive than others. There are three ways that prescribers interact with PDMPs.

Non-mandated use

The most common model is where the state operates a PDMP that is available to prescribers and dispensers (and sometimes others) and the use of the PDMP is voluntary. In this situation, it is desirable for practitioners to access the PDMP in a situation where they believe their prescribing (or dispensing) of a controlled substance may not be appropriate for a patient. North Carolina and Florida are two examples of states who operate with such a model.

Proactive reporting

Another model of the use of a PDMP is Massachusetts where prescribers and dispensers may voluntarily check the database but proactive reports are also sent to prescribers if any of their patients are getting a dangerous combination of medications or if they are visiting multiple doctors to get prescriptions.

Currently, 29 states provide unsolicited reports to prescribers and/or to law enforcement (PDMP TTAC, 2016a). The goal of these reports is to identify individuals who may be engaged in doctor shopping or who may be on a dangerous combination or dose of medication. Reports to law enforcement are to identify prescribers who are prescribing excessive controlled substances in a way that may be illegal.

The advantages of proactive reporting are:
PUBLIC HEALTH POLICY AND PDMP MANDATES

- This does not require the prescribers to actively search the database. As most prescribers in voluntary programs do not check the PDMP, this will discover more patients with abnormal behavior or dangerous combinations of medications.
- It does not require prescribers to interpret the data to determine if behavior is abnormal.

**Mandated use**

Kentucky, Tennessee, and New York are examples of states that mandate review of the PDMP by prescribers prior to giving prescriptions of controlled substances to patients. Other states also mandate some form of prescriber use of the PDMP but these 3 states have had comprehensive mandates for three years or more. A total of 32 states now have some type of mandate (PDMP TTAC, 2016b).

There are currently 11 states that require prescribers and dispensers to check the PDMP under certain circumstances. There are 22 states that required prescribers only (not dispensers) to check the PDMP and there are 18 states that do not require prescribers or dispensers to check the PDMP under any circumstance. (PDMP TTAC, 2016b)

The circumstance under which prescribers are required to check the PDMP can vary significantly. This can minimal like the state of NC where only the medical directors of Outpatient Treatment Programs (OTPs) that use methadone to treat opioid use disorder are required to check the PDMP on admission of each patient and annually after that. Or it can be quite comprehensive such as Kentucky where prescribers must check the PDMP prior to writing any controlled substance prescription, and at least every 3 months for patients who remain on controlled substances.
PUBLIC HEALTH POLICY AND PDMP MANDATES

Many states have implemented multiple public health measures to address the opioid issue. These may include:

- Improving access to naloxone – a critical medication that reverses opioid overdose.
- Passing “Good Samaritan” laws that allow those who call 911 to avoid arrest if they are also using illegal drugs.
- “Pill Mill” laws that reduce the number of businesses that exist simply to prescribe opioids and make profits with little or no regard to providing proper care to patients.
- Developing state prescribing guidelines that reflect appropriate prescribing of controlled substances.
- Improving access to medication assisted treatment (MAT) for OUD.

Of all policies implemented by state or federal government, mandating the use of the PDMP by prescribers may be the most intrusive/disruptive/costly depending on how extensive the mandate is.

State Experiences

Kentucky

Kentucky, for example, implemented its mandatory check requirement in July of 2012 and saw a dramatic rise in the use of the Kentucky All Schedule Prescription Electronic Reporting System (KASPER).

Benefits of Kentucky mandate.

Dispensing of controlled substances decreased from 7.39 million doses in the year prior to the mandate, to 6.76 million doses in the year following. (PDMP COE, 2016) Kentucky also saw a 50% decrease in “doctor shopping” which it described as: “a patient receiving multiple
prescriptions from four or more different prescribers and filled at four or more different pharmacies within a three-month period.” (Freeman et al., 2015).

**Cost of Kentucky mandate.**

A report to The Kentucky Cabinet for Health and Family Services in 2015 reports that heroin use and overdose appears to be growing faster in Kentucky than surrounding states but attributes this to the reformulation of OxyContin to an abuse-deterrent formulation more than the decreased availability of opioid pain pills (Freeman et al., 2015). As the distribution of reformulated OxyContin occurred across the country at the same time, it is unlikely that it would have affected Kentucky more than its surrounding states.

The year prior to HB1 there were 811,000 checks of KASPER by medical professionals. The year following there were 4,586,500. (PDMP COE, 2016) This represents an increase of 3,775,500 checks. If we make the following conservative estimates:

- The average physician salary is $200,000/yr. (Medscape source)
- The average physician works 3000 hours/yr.
- The average time to interrupt the visit, check KASPER, read and interpret results, and discuss with the patient is 1 minute.
- The average doctor sees 4 patients per hour.

We can then estimate that the additional 3,775,500 checks resulting from HB1 cost:

- 62,925 hours of physician time.
- 251,700 patient visits lost.
- The equivalent of 21 full time physicians
- $4,200,000 worth of physician time.
New York

New York has identified the opioid epidemic as one of its leading public health problems and has made multiple efforts to address this. In 2011-2013 they began an academic detailing project to educate prescribers in Staten Island regarding pain treatment and decreasing opioid use (Paone et al., 2015). In 2012, the Prescription Drug Reform Act was passed into law. This law contained several measures to address the opioid problem but the most significant change would be mandatory checks by prescribers of the NY PDMP. This began on 8/27/13.

Benefits of the New York mandate.

Despite the negative opinions of users, The New York State Department of Health believes that mandated use has had a positive effect by reducing doctor shoppers (Hopkins, Dreyzehner, & O’Leary, 2014; NYSDOH, 2016). New York reports an 82% decrease in doctor shoppers by the end of 2014 (New York State Dept. of Health, 2016).

Cost of New York mandate.

This law has not been popular with medical professionals who have generally found it burdensome and unhelpful. A recent survey of NY doctors found that 40.4% thought of I-STOP as “rarely” or “never helpful,” and 39.4% believed it was “difficult” or “very difficult” to use. The study also found that most disagree with the mandate and many do not obey it (Blum et al., 2016).

In the year prior to the law making it mandatory to check the NY PDMP, there were 132,000 requests to I-STOP. In the year following there was 15,439,500. (PDMP COE, 2016) This represents an increase of 15,307,500. A recent survey of NY physicians estimated that it takes an average of 3 minutes for each check of ISTOP (Blum et al., 2016). (This likely takes
longer in NY than KY because KY doctors may delegate the job of retrieving the information to other non-MD coworkers.) Otherwise, using the other assumptions that were used for Kentucky, we can estimate the additional costs of the I-STOP program:

- 765,375 hours of physician time.
- 3,061,500 patient visits lost.
- The equivalent of 16 full time physicians
- $51,025,000 worth of physician time.

**Tennessee**

Tennessee passed comprehensive Prescription Safety Act of 2012 and beginning April 1, 2013, prescribers have been mandated to check the PDMP prior to prescribing opioid pain medications. Tennessee Department of Health reports that there has been a 14.3% decrease in morphine milligram equivalents dispensed in Tennessee from 2012 through 2015 (TDOH, 2016).

**Cost of Tennessee mandate.**

Requests for reports by prescribers increased from 1,861,485 in 2012 to 5,062,732 in 2014 (TDOH, 2016). This represents an increase of 3,201,247 requests per year. Using the same assumptions used for Kentucky, we can estimate the additional costs of the I-STOP program:

- 53,354 hours of physician time.
- 213,416 patient visits lost.
- The equivalent of 17 full time physicians
- $3,400,000 worth of physician time.
Outcomes: Measuring the effectiveness of mandates

Mandating prescribers to use the PDMP appears to be the most effective way to maximize utilization of the PDMP. Kentucky, New York, and Tennessee are three states that have had the most comprehensive mandates (most prescribers must check the PDMP for most prescriptions) for the longest period. Each of these three states has measured outcomes that can be compared with other nonmandate states to assess their value. Each state has concluded that their own program is successful based on reductions in doctor shopping, opioid prescribing, and/or prescription opioid overdose deaths.

Reductions in doctor shopping, however, may not be an appropriate proxy measure. It is unclear who doctor shops and whether this represents diversion to other individuals or addiction by the patient. It also appears to be infrequent and not a major contributor to opioid addiction and overdose. (McDonald & Carlson, 2013)

The goal in any health program is to reduce morbidity and mortality. In the case of opioids, that means reducing the number of individuals who develop opioid use disorder and the number of those who die from an opioid overdose. Therefore, the most appropriate measure of the success of a program would likely be reduction in opioid overdose deaths. Research supports that individuals switch to heroin because of cost and ease of access (Mars, Bourgois, Karandinos, Montero, & Ciccarone, 2014). By reducing the supply of opioid pain medications to doctor shoppers heroin becomes cheaper and more accessible and it may inadvertently force individuals to change from opioid pills to heroin which has a higher risk of mortality. Therefore, overdose deaths must be measured counting prescription opioids as well as heroin.

So, the most important measure of the success of a mandated PDMP program would be to measure opioid overdose deaths and compare with other states that do not have a mandated
PDMP program. To understand the impact of the program on prescribing it is important to compare prescribing with other states that do not have a mandated program. Admissions to treatment may also be helpful to understand the status of those with OUD but this may be complicated by availability and affordability of treatment. It is estimated that the United States only has the treatment capacity to treat half of those with OUD (Jones et al., 2015). An initial trend showing an increase in treatment of OUD may be a positive result showing increased availability and accessibility of treatment.

**Outcomes for states with mandates compared to those without mandates**

Kentucky, New York and Tennessee have had the most comprehensive prescriber mandates for the longest periods of time starting in 2012 or 2013. To evaluate the impact of mandatory PDMP checks I chose to look at opioid overdose deaths (including both opioid pain medications and heroin) and opioid prescribing.

**Overdose Deaths due to opioids including heroin**

The reduction in overdose deaths is an important measure for the success of any policy addressing the opioid issue. Because state policy may force some to transition to heroin and because most heroin users began with prescription opioids, it is important to look at opioid pain medications and heroin when evaluating the effect of policies and programs on overdose death. Table 1 shows opioid overdose deaths in the three states with mandated prescriber PDMP checks compared with other states from the general region. Oregon is included to show that there can be dramatic regional variability in overdose deaths.
### Table 1: Overdose deaths due to Opioids including Heroin

<table>
<thead>
<tr>
<th>State</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>Increase 2012-2014</th>
<th>PDMP mandate effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kentucky</td>
<td>566</td>
<td>551</td>
<td>648</td>
<td>14.5%</td>
<td>7/20/2012</td>
</tr>
<tr>
<td>New York</td>
<td>1312</td>
<td>1446</td>
<td>1537</td>
<td>17.1%</td>
<td>8/27/2013</td>
</tr>
<tr>
<td>Tennessee</td>
<td>629</td>
<td>675</td>
<td>781</td>
<td>24.2%</td>
<td>4/1/2013</td>
</tr>
</tbody>
</table>

| No Mandate    |      |      |      |                   |                         |
| Florida       | 1261 | 1205 | 1379 | 9.4%              |                         |
| North Carolina| 791  | 782  | 915  | 15.7%             |                         |
| Georgia       | 491  | 489  | 678  | 38.1%             |                         |
| Vermont       | 49   | 60   | 58   | 18.4%             |                         |
| Oregon        | 315  | 259  | 294  | -6.7%             |                         |

| No PDMP       |      |      |      |                   |                         |
| Missouri      | 466  | 561  | 634  | 36.1%             |                         |
| Pennsylvania  | 756  | 858  | 994  | 31.5%             | PDMP start 6/2016       |

Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2014 on CDC WONDER Online Database, released 2015. Data are from the Multiple Cause of Death Files, 1999-2014, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/mcd-icd10.html on Oct 31, 2016 8:22:08 AM

**Opioid prescriptions dispensed**

State reports have claimed that PDMPs can be effective at reducing opioid prescribing. Some sources also credit mandatory checks with decreases in opioid prescribing. It is important to recognize that the entire United States had a decrease in prescribing from 2013-2015 of 9.8%. Compared to other regional states who did not mandate prescriber checks of the PDMP, mandating states had similar results (Table 2). It is not clear from the data that there is any decrease in prescribing from the mandate but there is some evidence that mandated checks change prescribing of opioids.
Table 2: Trends of number of Opioid analgesic prescriptions filled

<table>
<thead>
<tr>
<th>State</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>Decrease 2013-2015</th>
<th>Date mandatory checks effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kentucky</td>
<td>4,997,389</td>
<td>4,900,964</td>
<td>4,471,521</td>
<td>11.8%</td>
<td>7/20/2012</td>
</tr>
<tr>
<td>New York</td>
<td>10,957,729</td>
<td>10,450,786</td>
<td>10,164,060</td>
<td>7.8%</td>
<td>8/27/2013</td>
</tr>
<tr>
<td>Tennessee</td>
<td>8,525,017</td>
<td>8,239,110</td>
<td>7,800,947</td>
<td>9.3%</td>
<td>4/1/2013</td>
</tr>
<tr>
<td>No Mandate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Florida</td>
<td>13,636,391</td>
<td>13,413,544</td>
<td>12,708,441</td>
<td>7.3%</td>
<td></td>
</tr>
<tr>
<td>North Carolina</td>
<td>9,482,526</td>
<td>9,232,258</td>
<td>8,717,746</td>
<td>8.8%</td>
<td></td>
</tr>
<tr>
<td>Georgia</td>
<td>8,643,869</td>
<td>8,305,929</td>
<td>7,880,524</td>
<td>9.7%</td>
<td></td>
</tr>
<tr>
<td>Vermont</td>
<td>418,161</td>
<td>415,687</td>
<td>388,108</td>
<td>7.7%</td>
<td></td>
</tr>
<tr>
<td>Oregon</td>
<td>3,456,129</td>
<td>3,389,575</td>
<td>3,145,023</td>
<td>9.9%</td>
<td></td>
</tr>
<tr>
<td>No PDMP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missouri</td>
<td>5,755,659</td>
<td>5,602,998</td>
<td>5,217,577</td>
<td>10.3%</td>
<td></td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>11,330,259</td>
<td>11,031,159</td>
<td>10,394,466</td>
<td>9.0%</td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td>251,814,805</td>
<td>244,462,567</td>
<td>227,780,915</td>
<td>9.8%</td>
<td></td>
</tr>
</tbody>
</table>

Data provided by IMS Health. (IMS Health, 2016)

Changes in prescribing patterns.

A recent review of dentists in New York showed that mandated checks for dentists decreased opioid prescribing by 78% (Rasubala, Pernapati, Velasquez, Burk, & Ren, 2015). It is unclear why this happened but likely it was reducing the first exposure of opioids to patients as dentists usually prescribe for acute pain instead of chronic pain. Dentists are also the biggest prescribers of opioids to children (Volkow, McLellan, Cotto, Karithanom, & Weiss, 2011).

Baehren et al looked at emergency department prescribing before and after implementation of a mandatory PDMP check showed that it decreased prescribing to some but increased prescribing to others suggesting an increase in first exposure to opioids (Baehren et al., 2010).
which in turn may lead to an increase in future abuse and addiction (Edlund et al., 2014; Miech et al., 2015; Paulozzi et al., 2012).

**Conclusion**

Many states are trying to find the best way to utilize their PDMPs. Some states have mandated that prescribers request and check information from the state PDMP prior to prescribing opioids and other controlled substances. These states believe that this tactic must be successful because they have seen decreases in prescribing of opioids, opioid overdoses, and doctor shopping. However, reduction in doctor shopping may not be an appropriate public health goal as there is no clear evidence that it improves health or saves lives. While these states have also seen a decrease in prescribing of opioids, this reflects a national trend that is comparable to surrounding states. In fact, the entire nation has seen a decrease in opioid prescribing. Some of these states also note a decrease in opioid overdose deaths although when counted with heroin overdoses, their rates continue similar to other states with yearly increases.

The real cost of mandatory PDMP checks may not be fully understood by policy makers and public health officials. States that have mandated checks are utilizing large amounts of a very valuable resource: physician time. The development of single-focus policy that consumes so much physician capital is not wise. The unintended consequences that result from the lack of physician availability will be impossible to measure but likely will be considerable.

The opioid epidemic is a major public health concern in the United States. The CDC and others have recommended multiple public health measures to address it. Now that some policies have been in place for several years it is important to measure outcomes and adjust policy recommendations accordingly. Mandatory PDMP checks by prescribers consumes valuable
resources but have not provided significant improvements in outcomes. Knowing the natural history of opioid use disorder helps us to understand that interventions to reduce the opioid supply after individuals become addicted likely will not save lives as heroin is readily available throughout the United States. A recent study interviewed heroin users in NYC and found that the transition to heroin was much more likely after individuals became addicted to the opioids because heroin was cheaper and easier to obtain (Harocopos, Allen, & Paone, 2016). The main effect of mandatory PDMP checks is reducing doctor shopping which – for those with OUD – makes obtaining opioids more expensive and more difficult likely facilitating that change to heroin.

PDMPs can be valuable tools for the prescribing doctor. We must learn how we can best utilize them. Definitely, easy access can prevent overuse of physician time. They can help in the diagnosis of addiction which is a life-threatening disease. But when this diagnosis is made, treatment should be as available and affordable as any other medical treatment. They are likely also valuable in identifying doctors who overprescribe opioids.

The opioid epidemic is complex and has multiple drivers. The root causes of income inequality and poverty must be mentioned but are beyond the scope of this paper (Mulia, Schmidt, Bond, Jacobs, & Korcha, 2008; Siahpush et al., 2006). As with all epidemics, the best treatment is to prevent the spread of the vector. This will best result from a paradigm change to how we treat pain to use more effective yet less addictive medications and use opioids only rarely. We must also treat those who are already afflicted by opioid use disorder by improving availability and access to treatment.

There may be some technical solutions that could have an impact on opioid addiction and overdose:
• Laws that limit over-prescribing of opioids.

• Laws and rules that increase availability and access to treatment of OUD.

• Laws that decriminalize addiction and addiction-related behaviors and instead refer people to treatment.

Adaptive changes, however, will be needed for significant improvement. In the medical system, we must change how we understand and treat pain. We need to understand that the optimal treatment for acute pain seldom involves opioid pain medications (Teater, 2014). We must also understand that opioids should seldom be used for chronic pain (Dowell et al., 2016).

The medical community should lead adaptive change as they are the vector (prescribers) and the ones providing treatment for those afflicted in this epidemic. Some suggestions for adaptive change include:

• Physicians in public health must present unbiased and scientific recommendations for treatment of pain. A great example of this is the recent CDC guidelines for treatment of chronic pain (Dowell et al., 2016).

• State medical boards are tasked with protecting the public from poor health care providers. They must also be active in promoting safe and effective pain treatment to reduce opioid prescribing.

• National medical organizations should work to destigmatize addiction and make addiction treatment the standard of care for primary care practices.

Public education will also be very important as prescribers feel the pressure of time constraints and patient expectations and demands which likely results in increased opioid prescribing (Lembke, 2012).
PUBLIC HEALTH POLICY AND PDMP MANDATES

Using both adaptive and technical solutions we can begin to reduce the morbidity and mortality from the opioid epidemic. But it will be important that we continue to evaluation interventions to understand their true cost and benefit.
## PDMP Logic Model

<table>
<thead>
<tr>
<th>Resources</th>
<th>Activities</th>
<th>Outputs</th>
<th>Outcomes</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribers</td>
<td>Develop legislation</td>
<td>Legislation for Mandatory checks</td>
<td>Prescribers identify doctor shoppers</td>
<td>People with OUD get treatment of their disease</td>
</tr>
<tr>
<td>PDMP Program</td>
<td>Develop program for proactive reports</td>
<td>Proactive reports</td>
<td>Prescribers refer those with OUD to treatment</td>
<td>Lives saved</td>
</tr>
<tr>
<td>PDMP Staff</td>
<td>Educate prescribers on effective use of the PDMP</td>
<td>Prescribers use PDMP effectively and appropriately</td>
<td>Prescribers aware of unsafe medication combinations</td>
<td></td>
</tr>
<tr>
<td>Legislators</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Office Staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public Health Experts</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Addendum

Reflections on the recent presidential election results and new era for health care

With the election of 2016, Donald J. Trump is will soon become president of the United States. It is unclear how Mr. Trump’s presidency will affect the opioid epidemic along with overall health care. During his campaign he made several promises that could have significant effects.

One of his key promises was to repeal and replace the Affordable Care Act which would increase the number of uninsured by approximately 21 million by 2018. If this happens, we may expect the following:

- People needing or already involved in treatment for their opioid use disorder will not be able to afford it resulting in continuing or returning to active opioid use and worse outcomes.
- People with insurance who are on chronic opioid therapy for pain will no longer be able to afford their physician or medications and will result to illicit use of prescription opioids or heroin.

The President Elect also promised that he would turn Medicaid into a block grant program to control costs. It would then be up to each state to decide how to best treat those in their state with Medicaid. There would likely by wide variability on how well addiction is identified and treated from state to state.

Finally, when asked about his solution to the opioid problem, he replied that he was going to “build the wall” between Mexico and the United States. This really reflects his lack of
knowledge of addiction, the opioid problem, and root causes. Hopefully, as president he will expand his knowledge and his plan to address opioid abuse, addiction, and overdose.
References:


PUBLIC HEALTH POLICY AND PDMP MANDATES


pain-reliever-use-2013.htm


http://www.pdmpassist.org/pdf/Prescribers_Sol_Unsol_Reports_1.pdf


