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Mandatory review of a prescription drug monitoring program and impact on opioid and benzodiazepine dispensing

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ABSTRACT

Background: The purpose of this study is to determine whether Ohio House Bill 341, which mandated the use of Ohio's Prescription Drug Monitoring Program (PDMP), was an effective regulatory strategy to reduce opioid and benzodiazepine dispensing.

Method: Secondary analysis of Ohio's PDMP data on prescription opioids and benzodiazepines dispensed from November 2014 to March 2017. An interrupted time series analysis was conducted to determine if there was a significant change in the quantity of opioids and benzodiazepines dispensed.

Results: After HB341 became effective in April 2015, there was a statistically significant decrease in the monthly quantity (number of pills) opioids and benzodiazepines dispensed in Ohio. There was a modest increase in the mean days' supply of opioids and no change in the mean morphine equivalent dose.

Conclusions: Legislation in Ohio requiring prescribers to check the PDMP was effective in reducing the quantity of opioids and benzodiazepines dispensed.

1. Introduction

Drug overdose deaths in the United States (U.S.) have increased every year in the past decade, and in 2015 there were approximately 33,066 overdose deaths involving an opioid (Rudd et al., 2016). Increasing rates of drug overdose deaths have been associated with a parallel increase in prescription opioid sales, as well as treatment admissions for opioid use disorders from 1999 to 2008 (CDC, 2011); however, the national quantity of prescription opioids began to decline in 2012 (Guy et al., 2017). In the absence of the number of patients with legitimate pain that are being appropriately treated with prescription opioids, it's impossible to know the true excess of prescription opioids dispensed and how that has contributed to the misuse and diversion of these drugs. Annually, approximately 11.5 million people misuse prescription opioids (Han et al., 2017). More than 80% of people that initiate heroin use report that they first used prescription opioids (Jones, 2013) and 80% of people who abuse prescription opioids initiated use from legal prescriptions (Shei et al., 2015). Prescription Drug Monitoring Programs (PDMPs) are state-level electronic registries of prescription drugs dispensed, with the majority of the data being reported by community-based pharmacies for scheduled medications (Bao et al., 2016). Forty-nine states have implemented PDMPs (Manasco et al., 2016; Finley et al., 2017). Early PDMPs (the 1990s) were used to monitor and detect illicit distribution of schedule II medications, and while there is some variation across states regarding the purpose of the PDMP (Katz et al., 2008); many today are being used as a tool to monitor over-prescribing at the provider level and doctor-shopping (obtaining a similar prescription from multiple prescribers) at the patient level (Clark et al., 2012).

Research has evaluated the effectiveness of PDMPs as a regulatory tool to reduce the quantity of opioid prescriptions, the quantity of opioids dispensed, the mean days' supply of opioids, and the mean opioid morphine milligram equivalence (MME) (Bao et al., 2016; Rasubala et al., 2015; Finley et al., 2017; Brown et al., 2017; Brady et al., 2014; Rutkow et al., 2015). There is mixed evidence on the effectiveness of PDMPs (Finley et al., 2017; Griggs et al., 2015); which in

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part may reflect different levels of PDMP implementation and/or utilization, variation in the opioid drugs and/or drug schedules included in the analysis, variation in the outcomes measured (i.e., prescriptions written versus dispensed), variations in the prescribing setting (i.e., emergency department, dentist, etc.) and different state-level PDMP characteristics (Pew Charitable Trusts, 2016). For example, a 2001–2010 multistate comparison of prescriptions written for ambulatory pain patients found that PDMPs were associated with a 30% reduction in schedule II opioids; however, there was no impact on the overall number of prescriptions written for opioids (Bao et al., 2016). Florida's PDMP was associated with a reduction in the volume of opioids dispensed based on a claims dataset; however, this reduction was only statistically significant for high volume patients/prescribers and during this period Florida also passed pill mill legislation (Rutkow et al., 2015).

PDMPs, once implemented, take time to become fully operational. Their utility as a tool to detect doctor shopping relies on the timeliness of dispensing data, and they are unlikely to have a population-level impact until the majority of prescribers are using the PDMP. For example, Ohio passed PDMP legislation in 2006; in the early years, only approximately 25% of prescribers were using it (Burke, 2016). States also need staff and funding to identify over-prescribing, as well as to ensure that the appropriate steps are followed to investigate such cases. Prescriber utilization has increased with the integration of PDMPs within electronic medical records, and many states now require daily reporting of data. It is therefore not surprising that early PDMP studies reported mixed findings (Rutkow et al., 2015; Islam and McRae, 2014; Ringwalt et al., 2015; Chang et al., 2016); given the varying levels of PDMP implementation and utilization by prescribers.

Given the significant between-state variations in PDMPs (Manasco et al., 2016), there is an increasing amount of research investigating whether specific PDMP characteristics are associated with positive outcomes. Seventeen states mandate PDMP enrollment and only eight states require prescribers to review a patient's PDMP report before prescribing controlled substances (Manasco et al., 2016). Mandatory use of the PDMP is associated with decreases in the quantity of opioids dispensed, the number of opioids prescriptions and multiple provider episodes (MPEs) (Rasubala et al., 2015; Freeman et al., 2015; PDMP Center of Excellence, 2014). There is however mixed evidence regarding whether PDMPs reduce MME or days' supply, both of which are associated with increased risk of non-medical use and/or overdose (Guy et al., 2017; Paulozzi, 2012). Only one study has used PDMP data to report on benzodiazepine dispensing patterns; however, this study did not investigate the effect of PDMP implementation or regulations on benzodiazepine dispensing patterns (Paulozzi et al., 2015).

Ohio has one of the highest rates of overdose fatalities in the country and some of the highest rates of prescription drug trafficking (Rudd et al., 2016; Winstanley et al., 2012). The Ohio Board of Pharmacy reported that 8.2 million doses of prescription opioids were dispensed in just Scioto County alone in 2011, which was approximately 103.6 doses for every county resident including children (Ohio Department of Health, 2012). Legislation creating Ohio's PDMP, Ohio's Automated Rx Reporting System (OARRS), was passed in May 2005 and it became law in January 2006. OARRS is managed by the Ohio Board of Pharmacy, and it incorporates dispensing information on Schedule II–IV drugs and one non-controlled drug, gabapentin. There are approximately 2433 pharmacies, and 48,741 prescribers in Ohio registered to use OARRS. Ohio House Bill 341 (HB341) was first introduced on November 7, 2013, and it was passed on June 3, 2014; with an effective date of April 1, 2015. Rules, recommendations or guidelines previously existed to encourage prescribers to register to use OARRS or to check OARRS prior to prescribing; HB341 was the first legislative mandate that could be enforced. Ohio HB341 requires prescribers to check OARRS prior to initiating a prescription for opioids or benzodiazepines and subsequently re-checking OARRS every 90 days for patients who are continued to be prescribed these medications. HB341 incorporated exemptions to checking OARRS when prescribing or personally furnishing opioids and benzodiazepines when these drugs were for less than a seven-day supply, for hospice patients, for patients with a terminal illness or with cancer, and for patients prescribed opioids post-surgical procedures. Opioids and benzodiazepines administered in a hospital, nursing home or residential care facility were also exempt. Given that regulations may not have an optimal impact unless enforced, the Ohio Board of Pharmacy identified prescribers that were not in compliance with HB341. In August 2016, the Board mailed letters to prescribers that failed to check OARRS before prescribing an opioid or benzodiazepine, informing them they could be fined up to $20,000.

The goal of this project was to evaluate whether the effective date of House Bill 341 was associated with a reduction in the overall quantity of opioids and benzodiazepines dispensed in Ohio. The secondary goals were to evaluate whether HB341 was associated with a reduction in the days' supply of opioids or benzodiazepines, the mean MME per opioid prescription, and the number of multiple-provider episodes (MPE). Additionally, we investigated whether the HB341 enforcement letters further reduced the quantity of opioids and benzodiazepines dispensed. This study is unique from previous research as it includes all scheduled opioids indicated for pain and it accounts for opioid schedule changes in modeling the impact of PDMP regulations. Further, this is the first study to assess the impact of a PDMP on benzodiazepine prescribing practices.

2. Method

2.1. Data

A reduced dataset was provided by the Ohio Board of Pharmacy, including all records of reported dispensed medications from 2007 through the first quarter of 2017 (March 31, 2017). The dataset included information on the date filled, prescription number, prescription refill number, quantity dispensed, days' supply, national drug code, drug name, number of authorized refills, payment type, pharmacy business activity code, three-digit pharmacy zip code, patient age, patient sex, patient county, three-digit patient zip code, three-digit prescriber zip code, and prescriber specialty. The dataset included a de-identified unique code for patients, prescribers, and pharmacies.

2.2. Study population and sample

We restricted the data based on whom the bill targeted and was anticipated to benefit. Given that HB341 is only applicable to prescribers licensed in Ohio, we excluded records with an out-of-state prescriber, and only included patients who were Ohio residents. For this study, the dataset was restricted to medications dispensed between November 1, 2014, and March 31, 2017 (n = 52, 603,348). November 1, 2014, to March 31, 2015, was defined as the pre-intervention period, and April 1, 2015, to March 31, 2017, was the post-intervention period. The pre-intervention period was restricted to records after November 1, 2014, because of prior DEA opioid re-scheduling, which is known to have influenced opioid dispensing patterns. In August 2014, tramadol was reclassified from an unscheduled to a schedule IV drug, and in October 2014, hydrocodone was reclassified from a schedule III to schedule II drugs. Between 2007 to March 2016, hydrocodone represented 41.4% and tramadol represented 17.0% of all opioids dispensed in Ohio. Therefore, including opioid dispensing data prior to November 2014, would violate the assumptions of interrupted time series analysis. We developed code to classify opioids as either for the treatment of pain or addiction. The buprenorphine transdermal patch (Butrans), solution for injection, and film (Belbuca) were not categorized as medication-assisted treatment (MAT) because these formulations are indicated in the treatment of pain. Methadone solution was classified as MAT per Ohio regulations. Finally, methadone tablets were not categorized as MAT as they are indicated in the treatment of pain.