

Cohort Study

Mandatory Review of Prescription Drug Monitoring Program Before Issuance of a Controlled Substance Results in Overall Reduction of Prescriptions Including Opioids and Benzodiazepines

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Background: To date, there is limited research on whether the various types of mandatory usage of prescription drug monitoring programs (PDMP) have any effects on prescribing patterns, drug usage, patient care, and drug diversion (8-10). Within the United States (US), there is wide variation in individual states' requirements for the usage of PDMPs.

Objective: The objective of this study was to determine whether mandatory prescriber review of a PDMP prior to each issuance of a controlled substance resulted in a reduction in the total number of controlled substance prescriptions dispensed.

Study Design: A retrospective review of the State of Wisconsin's PDMP controlled substance database from April 2015 to March 2019 was performed. The evaluation compared the number of prescriptions among individual drug classes (opioids, benzodiazepines, stimulants) dispensed throughout the state before and after April 1st, 2017, when implementation of a state law mandating the review of the PDMP during each patient encounter prior to issuing a prescription for a controlled substance took effect.

Setting: Research was conducted using Wisconsin's PDMP controlled substance database from April 2015 to March 2019. During this time, controlled substance policy has come to the forefront of the nation due to issues with an opioid epidemic.

Methods: Descriptive analysis was used to express data as n and % for categorical data and average \pm standard deviation for numerical data. Before- and after-prescription totals were analyzed using a paired t test and Levene's test for equality of variances. The *P* value was considered significant at a level $\leq .05$.

Limitations: Limitations to this study included its retrospective design, focus on a single US state, and possible unforeseen contributors to cause and effect.

Results: Prior to the enforcement of the state's mandatory PDMP legislation, an average of 844,314 controlled substance prescriptions were written monthly. Following the implementation of the law, the average monthly total prescriptions written within the state decreased to 708,063. This was an average monthly reduction of 136,251 prescriptions written or 16.1%. Statistically significant reductions were also seen in opioid and benzodiazepine subgroups (23.0%, 16.3%).

Conclusion: Our study suggests that state-enforced mandatory usage of a PDMP, which records all controlled substance prescriptions filled by a pharmacy such as opioids, benzodiazepines, amphetamines, etc. at every encounter prior to prescribing any controlled substance, can provide for a significant reduction in controlled substance prescriptions, specifically opioids and benzodiazepines.

Key words: Prescription drug monitoring program, opioids, mandatory usage, benzodiazepines, Wisconsin

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Prescription drug monitoring programs (PDMPs) have existed for over 100 years in the United States (1). To date, all states excluding Missouri have a form of PDMP (Missouri's PDMP is county-based, not state-based) (2). This includes the District of Columbia and the territories of Guam and Puerto Rico. Each PDMP varies drastically in terms of collection of data, access, and requirements for review. Most states provide access to both prescribers and pharmacists dispensing the medications. While these individuals have the right to access the data, there are differences in regulations regarding when, who, and how often information is required to be reviewed.

As of January 2019, 33 states require mandatory enrollment in the PDMP for both prescribers and dispensers, 10 states require only prescriber enrollment, and only Guam requires dispenser enrollment (2). Enrollment in the PDMP only indicates that the practitioner has completed the required steps in order to access the drug-monitoring data. It does not actually require individuals to review the information available to them. Thus, many states have put into place further regulation to require usage.

Currently, 19 states require mandatory usage for both prescribers and dispensers, 25 require only prescriber usage, and one state, Oregon, only requires dispenser usage (2,3). Like the PDMPs themselves, each state drastically differs as to what is defined as mandatory usage. Many states, such as California, require PDMP usage prior to prescribing any schedule II, III, or IV controlled substance for the first time and subsequent review at least every 4 months if the medication is being utilized in continued treatment (4). Other states, such

as Vermont, have far more detailed requirements based on the type of medication, the schedule of the drug, the reason for usage/diagnosis, whether the patient is new to the prescriber/dispenser, whether it is a new or refilled prescription, the number of prescribers for the patient, and whether the prescription is being refilled in advance of the projected refill date (5).

The State of Wisconsin first launched its own statewide PDMP in 2013 with the goal of promoting safe prescribing and dispensing of opioids and other controlled substance prescription drugs (6). In 2015, the state passed Wisconsin Act 266, which mandated a practitioner to review a patient's PDMP record before the practitioner issued a prescription for a monitored drug (7). The state did allow some exemptions to the mandate for certain conditions (Table 1). Prior to the law's implementation, the state updated its PDMP in January 2017 to ensure ease of use for practitioners as well as to update software for enhanced workflow integration, data quality capabilities, and public health and public safety uses (6). On April 1st, 2017, the law requiring prescribers to review the PDMP prior to issuing a prescription for a controlled substance was placed into effect.

To date, there is limited research on whether the various types of mandatory usage of PDMPs have any effects on prescribing patterns, drug usage, patient care, and drug diversion (8-10). Thus, within the United States there is wide variation in individual states' requirements for the usage of PDMPs. As the country faces issues with controlled substances, in particular the opioid epidemic, we all look to develop tools to decrease availability and misuse. Our study set out to compare whether the implementation of a state law mandating the review of the PDMP prior to writing a prescription for a controlled substance at every patient encounter (excluding specific instances, see Table 1) had any effect on the number of monthly controlled substance prescriptions created.

METHODS

The study did not require institutional review board approval because it involved de-identified secondary data. We used publicly available data provided by the Wisconsin Enhanced Prescription Drug Monitoring Program which operates in accordance with the Wisconsin Statute 961.385 and Wisconsin Administration Code Chapter CSB 4. The Wisconsin Department of Safety and Professional Services (DSPS) oversees the operative of the PDMP in line with the policies established by the Wisconsin Controlled Substances Board (6).

Table 1. *Exclusion for mandatory prescription drug monitoring program (PDMP) before prescription issuance.*

The requirement for a practitioner to review a patient's PDMP records before prescribing a monitored drug does not apply in the following circumstances:
The practitioner is unable to review the patient's PDMP records because the PDMP digital platform is not operational or because of another technological failure, if the practitioner reports that failure to the controlled substance board (CSB).
The patient is receiving hospice care.
The prescription order is for a number of doses that is intended to last the patient 3 days or less and is not subject to refill.
The drug is directly administered to the patient.
Due to emergency, it is not possible for the practitioner to review the patient's PDMP records before issuing a prescription order for the patient.

The PDMP provides detailed information regarding many variables associated with the dispensing of controlled substances prescriptions since 2012. We assessed PDMP data over a 48-month period from April 2015 to March 2019 to determine the total number of controlled substance prescriptions written monthly. Subsequently, we determined the total amount of issuances per drug class (opioids, benzodiazepines, stimulants, and other). We divided our study period into 2 separate segments. The first segment was the 24-month period preceding the mandatory PDMP assessment prior to issuance of a controlled substance (2 years prior to April 1st, 2017). The second segment was the 24-month period following implementation (April 2017 through March 2019). During this time, the state's population increased from 5,759,744 to an estimated 5,820,000. The total growth of the state during this period was approximately 60,256 or 1.0% (11).

To compare the effect of mandatory PDMP usage prior to each individual issuance of a controlled substance, we utilized a paired t test to determine the difference before and after the intervention. We examined the monthly number of controlled substance prescriptions prescribed. In addition, we analyzed 4 subgroups: opioids, benzodiazepines, stimulants, and other. Examples of substances included in the "other" category are barbiturates, ketamine, and sedative-hypnotics such as zolpidem. Analysis was carried out using SPSS Version 22 (IBM Corporation, Armonk, NY). Descriptive analysis was used to express data as n and % for categorical data and average \pm standard deviation for numerical data.

Before- and after-prescription totals were analyzed using a paired t test and Levene's test for equality of variances. The *P* value was considered significant at a level $\leq .05$.

An additional analysis of the data in the 3 months preceding and following the update of the electronic prescription drug monitoring platform (January 2017) was assessed. This was to control for whether the update itself had any effect on controlled substance prescriptions. No significant difference was observed in prescribing patterns of controlled substances during that time interval in terms of the overall number of controlled substance prescriptions and individual drug class subgroup analysis.

RESULTS

From April 2015 until March 2017 a monthly average of 844,314 controlled substance prescriptions were written. Of the total number of prescriptions, 397,886 were prescriptions for opioids, 190,549 were for benzodiazepines, 140,726 were for stimulants, and 115,153 were for various other controlled substances. Following enforcement of the mandatory assessment of the prescription drug program before issuance of any control substance, the monthly average of controlled substances prescribed decreased to 708,063. This was a total reduction of 136,251 (16.1%) prescriptions per month. By subgroup, a total of 306,368 opioids, 159,508 benzodiazepines, 141,457 stimulants, and 100,713 other controlled substances were prescribed monthly (Fig. 1). Overall, there was an average monthly reduction

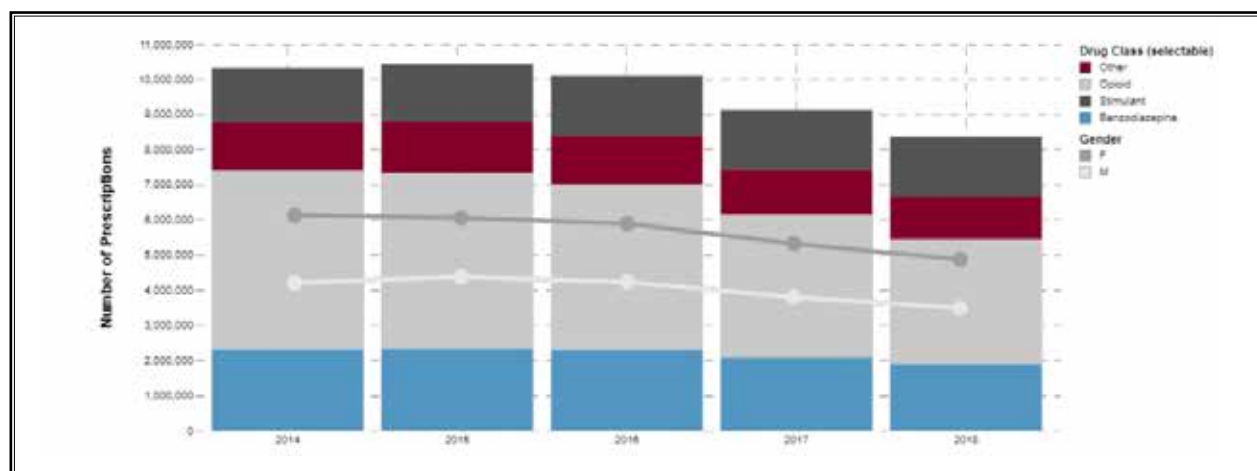


Fig. 1. *Dispensed controlled substance prescriptions by drug class annually for Wisconsin.*

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of 91,518 (23.0%) opioid prescriptions, 31,041 (16.3%) benzodiazepine prescriptions, and 14,438 (12.5%) prescriptions for other controlled substances. All these reductions were of statistical significance. During the same time period, there was an increase in the monthly

issuance of stimulant prescriptions (from April 2015 to March 2019), though this increase was not of statistical significance (Table 2, Fig. 2).

DISCUSSION

In 2017, the US Department of Health and Human Services declared a nationwide public health emergency regarding the opioid crisis (12). The Centers for Disease Control (CDC) estimated more than 11.5 million Americans aged 12 or older reported misusing prescription opioids in 2016 (13). During the preceding years, opioid prescriptions per capita saw a steady increase, especially within family medicine and internal medicine practices compared with other specialties (14). Thus, concerns regarding controlled substance misuse of particular opioids came to the forefront of the medical community. It was determined that prescription rates for opioids and other controlled substances fluctuate greatly by state and regions of the country without clear cause (15). Thus, systematic approaches such as PDMPs have become of increasing importance to monitor and prevent prescription drug use, abuse, and diversion.

As previously discussed, while most states have PDMPs, their availability, provider requirements, and utilization vary drastically (2-5). Prior studies assessing the efficacy of PDMPs and system interventions have demonstrated a positive correlation between PDMP usage and reduction of controlled substances, in par-

Table 2. Analysis of controlled substances prescription before and after mandatory PDMP assessment (April 2017).

	Group	Average Number of Prescriptions per Month
Total Prescriptions	Before	844,314
	After	708,063
	Change (n, %)	-136,251 (-16.1%)
Opioids	Before	397,886
	After	306,368
	Change (n, %)	-91,518 (-23.0%)
Benzodiazepines	Before	190,549
	After	159,508
	Change (n, %)	-31,041 (-16.3%)
Stimulants	Before	140726
	After	141457
	Change (n, %)	+731 (+0.01%)
Other	Before	115151
	After	100713
	Change (n, %)	-14,438 (-12.5%)

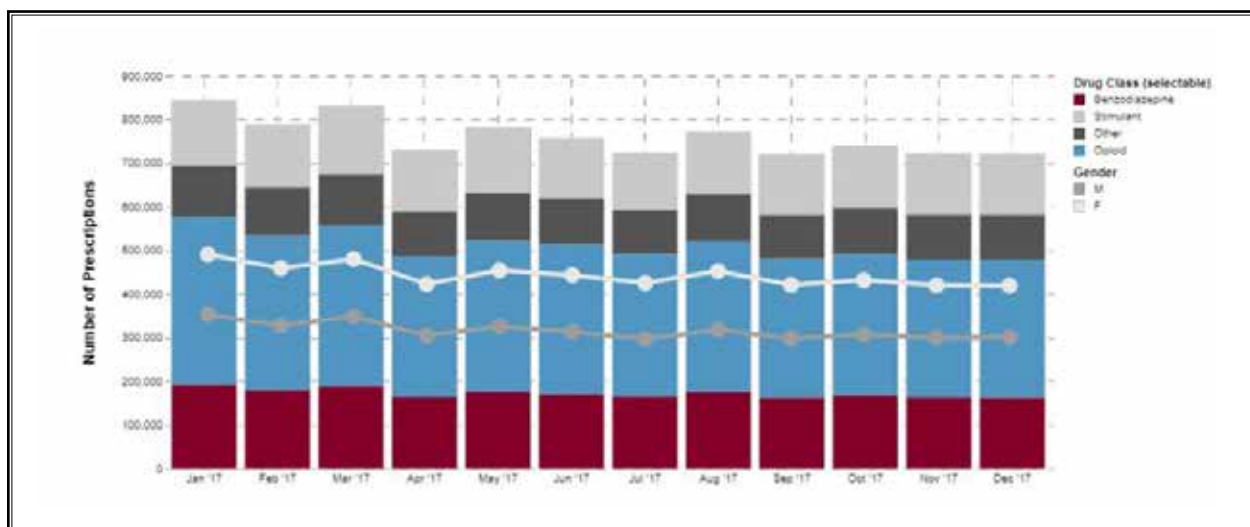


Fig. 2. Dispensed controlled substance prescriptions by drug class per month for 2017.

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ticular, opioids (6,8). Many of the flaws of prior PDMP assessments are due to a lack of data prior to intervention and difficulty defining specific interventions. This is made increasingly difficult due to differing degrees of participation from prescribers/dispensers (8,9).

Our study is one of the first to assess how mandatory use of a PDMP by all prescribers prior to the issuance of a controlled substance at every patient encounter can provide an overall reduction of total prescriptions, especially opioids and benzodiazepines. The State of Wisconsin had a functioning PDMP that collected prescribing data for 4 years prior and 2 years following introduction of the new law, making it possible to evaluate the intervention. We demonstrate a total average monthly reduction of controlled substance prescriptions by 16% during a period in which the total state population increased by more than 60,000 people or 1% (Fig. 1.). These results are of particular interest as they demonstrate how a systemwide mandate of a previously available system can provide a statistically significant change in prescribing patterns. This could be extrapolated to assume that most, if not all, states could decrease the number of controlled substances prescribed by implementing legislation promoting prescriber usage of their PDMP. Our findings demonstrate that mandated PDMP use leads to a reduction in both opioid and benzodiazepine prescriptions, while preserving the number of other substances such as stimulants. This may be viewed as a targeted intervention against 2 problematic medication classes within the context of the ongoing opioid epidemic (15,16). This reinforces the findings of previous studies demonstrating that legislative changes can affect outcomes surrounding opioid prescribing and diversion (17,18).

As previously mentioned, our study demonstrated that mandatory review of a PDMP can decrease opioid and benzodiazepine prescriptions. It was interesting to the authors that the number of stimulant prescriptions was preserved or slightly increased. While there

is no current research that provides clear insight into this observation, we surmise that these drugs may be perceived as “safer” by prescribers or as being under greater scrutiny within the medical community and society as a whole. Stimulants, like all medications, should not be prescribed without careful assessment of the risk and benefits. We believe further research on this observation both within our state and nationally is warranted.

Our study has several limitations. This is only a retrospective review of one state’s PDMP controlled substance database between 2015 and 2019 and not a randomized controlled trial. Furthermore, throughout the years of the study, the United States and many of its governing bodies had a strong focus on the opioid epidemic, which may have influenced prescription patterns within the state. Finally, Wisconsin has a comprehensive PDMP that provides a multitude of features, including data-driven alerts for events such as early refills, multiple prescribers, and concurrent opioid/benzodiazepine prescriptions, which may have augmented the effects seen in this study.

CONCLUSION

System-based interventions such as PDMPs are important tools to reduce the abuse, misuse, and diversion of controlled substances. These programs exist in the majority of states nationwide; however, we argue that they are only effective if they are actually put into use by practitioners. Importantly, even though the number of states that require mandatory PDMP monitoring by prescribers is increasing, the actual definition of that monitoring in terms of frequency, diagnosis, and situation varies greatly. Our study provides evidence that the legal mandate for prescribers to consult a PDMP every time a controlled substance is issued can provide for a total reduction in the number of controlled substance prescriptions within that state.

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