

Effects of Implementation and Enforcement Differences in Prescription Drug Monitoring Programs in 3 States: Connecticut, Kentucky, and Wisconsin

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ABSTRACT

BACKGROUND AND AIMS: Prescription Drug Monitoring Programs (PDMPs) were designed to curb opioid misuse and diversion by tracking scheduled medications prescribed by medical providers and dispensed by pharmacies. The effects of PDMPs on opioid prescription, misuse and overdose rates have been mixed due in part to variability in states' PDMPs and difficulties measuring this complexity, and a lack of attention to implementation and enforcement of PDMP components. The current study uses qualitative interviews with key informants from 3 states with different PDMPs, Connecticut, Kentucky and Wisconsin to explore differences in the characteristics of the PDMPs in each state; how they are implemented, monitored and enforced; and unintended negative consequences of these programs.

METHODS: We conducted in-depth interviews with key informants from each state representing the following sectors: PDMP and pain clinic regulation agencies, Medicaid programs, state licensing boards, pharmacies, emergency medicine departments, pain management clinics, first responders, drug courts, drug treatment programs, medication assisted treatment (MAT) providers, and harm reduction organizations. Interview guides explored participants' experiences with and opinions of PDMPs according to their roles. Data analysis was conducted using a collaborative, constant comparison method.

RESULTS: While all 3 states had mandated registration and reporting requirements, the states differed in the implementation and enforcement of these and the extent to which provider prescribing was monitored. These, in turn, influenced how medical providers perceived the PDMP and changed how providers prescribed opioids. Unintended consequences of state PDMPs included under-prescribing for pain and "dumping" patients who were long term users of opioids or who had developed opioid use disorders and may explain the increase in illicit heroin or opioid use.

CONCLUSION: State PDMPs with similar mandates may differ greatly in implementation and enforcement. These differences are important to consider when determining the effects of PDMPs on opioid misuse and overdose.

KEYWORDS: Opioids, overdose, prescription drug monitoring programs, implementation, enforcement

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Introduction

Prescription and illicit opioid (eg, heroin, fentanyl) misuse and associated harms such as fatal overdose have become a public health emergency in the United States.¹ In 2018, approximately 10.3 million people in the United States misused opioids and 46,802 people died of opioid overdose.^{2,3} This fatal overdose rate reflects an increase of 345% between 2001 and 2016, with particularly steep increases since 2015 due to increasing use of illicitly manufactured synthetic opioids such as fentanyl and carfentanil.⁴ The opioid epidemic has moved through several phases, starting in the 1990s with excessive prescriptions of opioids, followed by diversion and the growth

of an illicit market, the shift to heroin starting around 2010 and then a spike in illicit fentanyl-involved deaths starting around 2014.⁵

State Prescription Drug Monitoring Programs (PDMPs) were designed to curb opioid misuse and diversion by tracking scheduled medications prescribed by medical providers and dispensed by pharmacies.⁶ All states except Missouri have PDMPs in effect, although considerable variation exists in when these were implemented.⁷ PDMPs were predicated on the idea that reducing excessive prescribing among medical providers or overlapping opioid prescriptions from multiple providers would reduce the supply of prescription opioids available for diversion



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and nonmedical use of prescription opioids.⁸ PDMPs have been shown to change physician prescribing behavior after implementation in terms of the number of days opioids are prescribed⁹⁻¹¹ and morphine milligram equivalents (MMEs) prescribed.^{12,13} Overall, opioid prescribing rates have been shown to decrease in some states after implementation of PDMPs,¹⁴ but no significant changes have been found in others.⁶ Studies on the effects of PDMPs on opioid overdoses have similarly been mixed with some studies finding no change in overdose following PDMP implementation,¹⁵ and others finding an increase in overdose.¹⁶ In addition, there has been considerable concern among researchers that the rise in heroin use and overdose starting in 2010 may have been an unintended consequence of policies like the PDMP that reduced the supply of prescription opioids for nonmedical use.^{7,17-19}

The lack of clear answers about the intended and unintended effects of PDMPs may be due to a simplistic categorization of states as either having PDMPs present or not.^{18,20} States developed their own PDMPs and studies have characterized important differences among them, for example the frequency of reporting requirements or whether or not PDMPs conduct proactive investigations of prescribers or dispensers. Furthermore, sets of individual PDMP components are typically implemented together making it likely for studies that attempt to assess the effects of a single PDMP characteristic on overdose to conflate clusters of PDMP characteristics implemented together. Some differences in study results can also be attributed to differences in the dates different data sources assign to when PDMP laws became enacted, became operational and required prescribers and/or dispensers to query the PDMP before writing or filling a prescription.²¹ Also, states' PDMPs have changed over time, but most studies do not account for heterogeneity in PDMPs within states over time.²¹ Finally, the decision to enact stricter PDMPs over time does not happen in a vacuum but is likely the result of the nature of opioid overprescribing and overdose problems within a state, along with other contextual factors.²⁰

Some research has attempted to assess the effects of differences in PDMPs to outcomes such as increased heroin use or overdose deaths. Modeling studies have suggested that PDMPs may decrease prescription opioid misuse but increase heroin and fentanyl use.²²⁻²⁵ Pardo and colleagues created a measure of PDMP "robustness" by aggregating the number of regulations in states' PDMPs and then assigning ad hoc weights to different legislative components.²⁶ However, these components were weighted according to limited existing evidence or beliefs that the regulations were effective in reducing opioid deaths or changing opioid prescription behaviors. Meadowcroft and Whitacre used multiple correspondence analysis (MCA, an extension of principle components analysis) to measure the strength of PDMP robustness. They found a single binary variable that required physicians to access the PDMP before writing opioid prescriptions showed a strong positive association with heroin deaths, supporting the theory that more stringent

state PDMPs are associated with higher rates of heroin-related deaths, potentially due to decreases in prescription opioid availability.¹⁸

Research studying the effects of PDMPs on opioid misuse and overdose has also largely ignored differences in the implementation and enforcement of PDMP regulations.²⁷⁻²⁹ For example, although both the Smith et al²⁰ and Meadowcroft and Whitacre¹⁸ studies examined specific characteristics of PDMPs, the researchers relied on binary measurement of these characteristics. In these studies, a characteristic, like mandated use, is either present or absent and the degree to which these characteristics are implemented or enforced is not considered. States may differ in their implementation due to factors such as the extent of efforts to educate medical providers about the PDMP and its requirements, or its integration into electronic medical records (EMR) facilitating its use.²⁷ Enforcement can differ on how states proactively monitor compliance with system registration, required PDMP queries, audits of prescribing outliers, and reports of red-flagged prescribers to state medical licensing boards.²⁷ Enforcement may also be limited by implementation barriers such as limited resources.²⁷ Qualitative research has identified some key factors influencing implementation of PDMPs such as linkage to electronic health records (EHR),²⁹⁻³¹ and communication barriers between physicians and pharmacists.^{32,33} In addition, qualitative research has illuminated the perceived unintended consequences of the PDMP by PDMP staff, law enforcement officials, and administrative agency employees.¹⁷ However, these studies have not focused on how implementation factors such as monitoring and enforcement vary by state or how these differences may influence the perceived unintended consequences of the PDMP.²⁸

The current study uses qualitative interviews with key informants from 3 states with different PDMPs, Connecticut, Kentucky and Wisconsin. We explore differences in the characteristics of the PDMPs in each state; how they are implemented, monitored and enforced; and unintended consequences of these programs. Research questions to be answered include the following. How are PDMPs implemented in each state? How is compliance with PDMP mandates monitored and enforced? How does the PDMP change physicians' prescribing practices and do these vary with differences in state's implementation, monitoring and enforcement? Finally, are there unintended consequences of these changes in prescribing practices? The paper first describes differences in how the PDMP is implemented in each state, and then the effects of the PDMP on physicians' perceptions and prescribing patterns. Finally, we will explore perceptions of the unintended consequences of the PDMP.

Methods

Study overview

The current study is part of a larger project that aims to compare the factors that influence the effects of opioid-related laws and policies in Connecticut, Kentucky and Wisconsin on the

transition from prescription opioids to heroin, fentanyl, and injection drug use. An urban, suburban, and rural area was selected in each state to examine the role of the local context on the transition from prescription opioids to heroin, fentanyl, and injection drug use.

The 3 states chosen for this study reflect differences in prescription opioid and heroin/fentanyl use and their PDMPs.^{34,35} Connecticut has long had a problem with heroin starting in the 1960s and continuing to the present. Starting in the 1990s, prescription opioids were sold on the street and misused. Street fentanyl is now the most common street-level opioid. It has a rate of past year opioid use or dependence of approximately 9.5%.³⁶ Kentucky, on the other hand, began its opioid crisis with the over-prescription of opioids in the 1990s. As patients began to use prescription opioids non-medically, injection drug use became more common. Heroin use is still relatively rare. The rate of opioid use disorder is approximately 11.7%.³⁶ Finally, Wisconsin is intermediate in terms of heroin and prescription opioid use. While heroin use remained common, if not prevalent in Milwaukee, non-medical prescription opioid use also became very common, particularly in the suburban and rural areas of the state.³⁷ It has an OUD rate of approximately 4.9%.³⁶

Study teams in each state conducted in-depth, semi-structured interviews with 2 groups: key informants and people who use heroin or prescription opioids nonmedically. The present paper uses data from key informants who were able to comment on the structure, implementation, monitoring and enforcement of each state's PDMP. Key informants included PDMP and pain clinic regulation agencies, Medicaid programs, state licensing boards, pharmacies, emergency medicine departments, and pain management clinics. We also explored how PDMPs have changed opioid misuse in the states, including changes in drugs available on the street by interviewing first responders, drug treatment providers, medication assisted treatment (MAT) providers, and harm reduction organization personnel. We identified an initial list of key informants using the expertise of the research teams located in each state. To be eligible, key informants had to be at least 18 years old and currently working in the specific sectors of interest. We used purposive sampling in each local area within each state to ensure that each of these roles was covered in the initial list. We then asked key informants for the names of additional people who occupied other key roles. We conducted 34 key informant interviews in Connecticut and 63 in both Kentucky and Wisconsin, for a total of 160 interviews.

Potential participants were contacted by an email in which they were given a brief description of the study and told why they were being asked to participate. If these candidates expressed interest, interviewers scheduled a time to conduct a face-to-face interview when possible, or a phone interview. All participants were told that their participation was voluntary and would be kept confidential and each provided written informed consent to participate in the study. Interviews lasted approximately 30 to 60 minutes and were audio recorded. All

procedures were approved by the Institutional Review Board at the Medical College of Wisconsin.

Interview content. Interview guides and probes differed depending on the sector to which participants belonged. All key informants were asked to describe their current job and responsibilities, and to assess the extent of prescription opioid misuse in their communities and factors that have contributed to it. The current paper focuses on key informants' perceptions of their state's PDMP including how it formed and changed over time, mandates requiring its use by medical providers and for controlled substances, how compliance is monitored and/or enforced, and difficulties implementing the PDMP. We asked physicians how the PDMP changed their medical practice, if at all. We asked first responders and substance use treatment providers their perceptions of how opioid and illicit drug use has changed over time and what effect, if any, the PDMP may have had on this.

Data analysis

All interviews were transcribed verbatim. We used a collaborative approach for data analysis. First, we selected a transcript that was read by the multi-state research team to develop a preliminary list of codes. The preliminary coding list was then applied to 3 additional transcripts—which were purposively selected to reflect different experiences (eg, the sector to which the key informant belonged, state, local area)—and refined until the research team reached consensus on a final list of codes, their meanings, and the procedures for assigning them to text data. The research team then used MAXQDA software to apply the final list of codes to the transcripts. The coding was completed by 6 members of the multi-state research team. Coding, development of new codes, and memoing (jottings done by coders to capture relationships between codes or initial hypotheses) were tracked by the 6-person team. We also used bi-weekly team meetings for troubleshooting and quality checks that included the principal investigator of the study.

We used a constant comparative approach to analyze data for this paper. First, we compared what key informants from different sectors or different areas of the state had to say about the PDMP. We then compared states to each other to identify differences and similarities in states' PDMPs and how they were implemented. This analysis resulted in the identification of major themes: the implementation and enforcement of mandated use requirements; data use to monitor prescribers; perceptions of the uses of the PDMP; effects of the PDMP on prescribing practices; and unintended consequences of the PDMPs. In all areas, differences and similarities were discovered. Participant roles and state are identified at the end of the quotes to the extent possible while still maintaining participant confidentiality. In presenting results, "the majority," "most" or "nearly all" refers to over 90% of participants, "many" to over 50% to 90%, and some to between 20 and 50%.

Table 1. Key informant type by state.

CATEGORY	CONNECTICUT	KENTUCKY	WISCONSIN	TOTAL
Behavioral health	6	29	16	51
Drug court	0	4	8	12
Emergency department	4	0	4	8
First responder	6	11	10	27
Harm reduction	7	3	5	15
Licensing board	1	1	0	2
MAT provider	2	0	3	5
Medicaid reviewer	0	4	0	4
Pain management	2	0	3	5
PDMP	1	3	2	6
Pharmacist	3	2	5	10
Physician (Non-ED or MAT providers)	1	0	0	1
Policy/law	0	6	2	8
Public defender and district attorney	1	0	5	6
Total	34	63	63	160

Results

The numbers and roles of different key informants interviewed are presented in Table 1. A list of implementation factors and how they differed among the 3 states is included in Table 2.

Implementation and enforcement of mandated use requirements

Connecticut, Kentucky and Wisconsin currently have PDMPs that require prescribers to register with the PDMP and to query the PDMP prior to prescribing opioids.³⁸ Kentucky was the first of the 3 states to have a PDMP and was the first to move to mandatory registration and reporting in 2012, followed by Connecticut in 2015, and Wisconsin in 2017.³⁸ Kentucky's PDMP changed from merely being a tool that had no requirements for prescribers to register or use it, to mandatory registration for prescribers, to mandatory queries before prescribing greater than a 72-hour supply of a controlled substance. This trend has been followed in most states, as it was found that use of the PDMP increased with mandatory registration and use, and that opioid prescriptions decreased.³⁸ However, while the 3 states' PDMP enrollment and use are similar, the compliance and enforcement with these mandates differ.

While all 3 states have moved over time to requiring all prescribers of controlled substances to register with the PDMP and to check it prior to dispensing more than 3-day supplies, the states vary in the extent to which physicians currently comply and what regulatory agencies, such as the PDMP and state licensing boards, are currently doing to ensure compliance.

State employees in Connecticut suggested that compliance monitoring is still focused on making sure all physicians are registered in the PDMP.

So, we have a number of different potential remedies for PMP [i.e. PDMP] related violations but there's really two. Well, so, when you start to talk about practitioners, they have very specific requirements with the PDMP. First, they have to be registered to use it. And two, they have to use it in certain circumstances. And so, we still do a lot of education in those areas and we're, we've recently identified prescribers that appear not to have a registration. But we're doing a lot of significant contact management to identify the right people, but we're giving everybody an opportunity to get registered in what I believe is a fair way. (CT state employee).

Wisconsin state employees reported that they are focused not just on making sure that prescribers are registered, but that they are checking the PDMP when prescribing controlled substances which is measured through a compliance log.

So, the PDMP logs all activity. There is a comprehensive log of all queries made of patients in the system. Then, at its essence, the PDMP is a database of all prescription-controlled substance prescriptions dispensed in the state. So, we do have these two logs and we are able to look to see if specific providers have looked up specific patients. We know what the patients have [been] prescribed and we know whether or not they have looked up those patients and when they looked up those patients (WI state employee).

The Kentucky PDMP conducts regular proactive audits in addition to making sure that prescribers are registered and checking the PDMP. For example, they check the database to

Table 2. Characteristics of PDMP implementation by state.

	CONNECTICUT	KENTUCKY	WISCONSIN
Mandated use	Focused on compliance with registration. Education.	Compliance log to ensure use	Compliance log to ensure use
Integration with EHR/state sharing	Partial	Partial	Partial
Interstate sharing	Capacity but no systematic use	Capacity but no systematic use	Capacity but no systematic use. Physicians lack knowledge of capability
Law enforcement	Subpoena required	Can be used in an active case, no subpoena required. PDMP contains non-fatal overdoses and drug convictions. Special drug enforcement unit in PDMP.	Can be used in an active case, no subpoena required. PDMP contains non-fatal overdoses and drug convictions. Includes lost or stolen prescriptions.
Peer comparison reports	Sent to prescribers	Sent to prescribers. Report of patients who had overdose sent to prescriber	Sent to prescribers.
Physician prescribing	Review triggered by complaint	Review triggered by complaint. Quarterly audits performed on specialties or prescription drugs.	Review triggered by complaint and sometimes audits conducted.
Licensing board standards	Licensing boards and PDMP do not directly work together to set standards or audit.	Licensing boards determines appropriateness of prescribing practices and sets parameters for audits.	Licensing board determines appropriateness of prescribing practices and sets parameters for audits.

identify top prescribers of controlled substances to investigate further.

There used to be, let's call it the KASPER [Kentucky All Schedule Prescription Electronic Reporting, PDMP] Advisory Council and I was on that. And that council would kind of set parameters on, we would ask for reports. In other words, the council would say, "We'd like for you [PDMP investigators] to write a report on the top five percent of prescribers who are prescribing Xanax and opioids comingled." And then we would turn that over to the pharmacy investigators at KASPER to see if there's something going on here. And if so, they would report it to the Kentucky Board of Medical Licensures, or the Nursing Board, or the Dental Board, whichever one is the appropriate one. (KY state employee)

All 3 states have also tried to make their PDMPs easier to use by integrating them with existing electronic health record (EHR) systems, also known as electronic medical records (EMR). Prescribers can press a single button on their EHR to check the PDMP. Connecticut was most recent in making this change. However, none of the states is able to provide universal integration because of the multitude of different EHR systems in use.

Part of the development was to try to make the access of the PDMP easier. One way to do that was through a single sign on offering so a prescriber doesn't need to navigate to the PDMP website but can get a button within the electronic medical record for a specific patient and get that single-click access. It's not something that's universal for all users. There are 14 health systems in about 40 percent of our queries, but that EHR single sign on has also increased awareness and ease of use of PDMP and some of the buy-in and ultimately success (WI state employee).

In addition to making compliance easier, integration into EHRs can force compliance by making prescribers check the

PDMP when they prescribe medications for which they are required to check.

So, I mean in terms of prescribing, EPIC has a stopgap. So, if you prescribe more than X amount of pain medications, you know, when you prescribe any opiate it brings up a list of click boxes. You have to click them. . . . I have to click a button there so I'm almost obligated to do one or two of those things. Either prescribe less than the amount that's required or check the PDMP (WI Emergency Department physician)

All 3 states' PDMPs also include interstate sharing. Wisconsin currently shares data with 17 different states including all border states, Illinois, Minnesota, Michigan and Iowa. Kentucky shares with 12 states including 6 out of 7 of the border states: Ohio, Tennessee, West Virginia, Virginia, Illinois and Indiana (except for Missouri which does not have a PDMP). Connecticut shares with 39 states including all border states (Rhode Island, Massachusetts, and New York). However, physicians are not mandated to check other states, and, in some cases, physicians seem to be unaware that the capacity to check other states exists.

Here, I don't think we can see Illinois in ours, or Michigan, or—we don't see the border states. We're so close to the border that it wouldn't be unheard of for the patients to be going to Illinois to get something. (WI Emergency Department physician).

There is also a question of how useful checking border states is for physicians, particularly without any guidance on which patients should be checked and for which states as suggested by Kentucky state employees.

P: It didn't take them long to figure out that, "Well, if I'm shopping only in Kentucky, they're going to catch me.

But I can zip over here to Indiana, and Ohio, and Illinois, and that data is not in KASPER. Maybe no one will detect it.” So, that’s why the interstate data sharing is so important now.

- I: Have you found that that’s become pretty effective in helping to catch people who do that?
- P: That’s a great question. We’re actually trying to spearhead a project on informed interstate sharing to help our users determine when does it [help] because there’s a lot of noise right now. You know, you query, some people will say, “Let’s query all of the border states.” . . . Is there a way we can actually analyze the data and use some data analytics to even suggest to our practitioners, “For this patient, you may want to query this state as well,” or something like that?

Checking the PDMPs of all border states may lead to confusion because of similarities in names. The PDMP employee above is suggesting that queries to other state’s PDMPs should be more targeted, for example to the closest bordering state or in circumstances that might lead prescribers or dispensers to believe patients might be filling prescriptions in other states. For example, a pharmacist in Kentucky might want to check Indiana’s PDMP if a patient whose residence is in Indiana comes to fill a prescription.

Each of the 3 states’ PDMPs can be used by law enforcement. In Wisconsin and Kentucky, the PDMP can be used for specific and ongoing cases. Law enforcement access to Connecticut’s PDMP is more restricted and requires not only an active investigation but also a subpoena and court order or approval.³⁸

Law enforcement in Kentucky can access it if they have an open bona fide drug investigation, and it specifies an individual by name. So, they could do doctor-shopper investigations, and they can also do investigations of individual prescribers, or pharmacists, or even pharmacies for that matter (Kentucky state employee).

Kentucky and Wisconsin also record non-fatal overdoses and any drug arrests or convictions into the PDMP which can then be seen by prescribers.

It’s been greatly improved the last three or four years. So, now a prescriber can go in and see criminal justice data on a patient, whether or not they’ve been convicted of a drug offense. Now a prescriber can go in and to the Kentucky Health Information Exchange and find out if you’ve been in the hospital for an overdose. We thought that was extremely important. Then if you’re prescribing someone a controlled substance and they’ve overdosed on it last weekend. . . . And if the patient didn’t tell you, you wouldn’t have any way of knowing that. Now you have a way of knowing that (KY state employee).

Wisconsin also reports lost or stolen prescriptions to the PDMP.

Data use to monitor prescribers

All 3 states provide prescribers with “peer comparison reports” so that they can compare their prescribing to other providers.

While this is ostensibly meant as an educational tool to help them in their prescribing practices, it also may have a deterrent effect.

He’s [PDPM regulator] doing all these things with the PMP so that providers can look at their group of providers, general surgeons and see, “Am I prescribing a lot of opioids? Am I hitting the average? Am I lower than normal?” But it makes people a little paranoid. For instance, our, I call ‘em midlevel practitioners because they can be APRNs [Advanced Practice Nurse Practitioners] or PAs [Physician Assistants], they, we had a meeting about this yesterday, because they were paranoid because when they look, they’re prescribing more than the average amount of narcotic, and they’re saying, “Oh my God, the state is gonna come after me.” You know, they’re looking at me and so I asked [PDMP official] about this and he said, “No.” He said, “Don’t have them be paranoid.” When they compare themselves, they’re comparing themselves to all the other PAs or all the other APRNs in Connecticut, so it’s not just like general surgery PAs that they’re comparing themselves to, it’s everybody. And he said a lot of ‘em may not even use narcotics so that brings the average down. So, he said, you know, don’t be paranoid, although he says he doesn’t mind if they’re a little paranoid (CT Pharmacist).

Wisconsin and Kentucky also provide prescribers with “report cards” which give more detailed information about their personal prescribing history and their ranking compared to prescribers of the same specialty.³⁹ These can also have a similar deterrence effect because, as the participant below suggests, nobody wants to be an outlier.

We now are doing what we call prescriber report cards through KASPER that is sent to a physician or nurse practitioner once a year to say, “Here’s how your peers [in your specialty] prescribed. Here’s how you prescribe.” Most people don’t want to be an outlier. They want to be right there in the middle. So, if they see that I’m prescribing it a lot more than anybody else, that may change [prescribers’] behavior (KY state employee).

Kentucky also sends “death notices” to prescribers who have prescribed opioids to patients who have subsequently died of overdose.

States vary in the extent to which the PDMP is used to proactively find physicians who are over-prescribing or not complying with the requirement to check the PDMP. Connecticut only investigates compliance, and cases in which there were complaints against physicians. Complaints are often generated by patients or by family members, and PDMP personnel characterize many of the complaints as “vindictive” and a result of perceptions of poor customer care.

- I: How do you identify a physician who may be over prescribing. . . ?
- P: Uh, well, usually it’s by complaint. In general, to date, we have not used the PMP to just exclusively identify people that way. We want that PMP to be a tool first for the prescribers. We will use it when we get a complaint, but we have not done a lot of proactive data analysis on over prescribing. And it’s. . . If you’re really

going to do it, you need to do it with a really thoughtful, robust algorithm. And I don't have the resources to create that here, so I would need to purchase something, and even still, I worry about that and how that makes the PMP perceived, because I really want people to use it. . . . But, you know, when you start to think about the data that's in there, a pain management physician is going to have many patients with opioids with high MME scores, morphine milligram equivalence, and look on paper, it's very easy to categorize them as good or bad, right? But there's a lot more that goes into it than just looking at data. (CT state employee).

The Connecticut PDMP does not have systems in place to identify the level of prescribing that is appropriate or not and does not seem to have worked with licensing boards to set criteria according to medical specialty. It is also the only state of the 3 in which state licensing boards do not have access to the PDMP. Rather, the Connecticut PDMP seems to want to avoid being seen as a disciplinary body because they are still trying to get people to use it as a clinical tool. The 3 states differ in the number of full-time personnel they have working in the PDMP, which may affect their ability to conduct proactive audits. Connecticut's PDMP currently has 13 full time employees, Kentucky has 36, and Wisconsin only has 2 but works with other agencies.

In the past, Wisconsin also mostly responded to complaints in deciding to investigate prescribers. Audits are a relatively new practice for Wisconsin by the Controlled Substances Board (CSB) and licensing boards of the various medical specialties.

So, part of that falls on the Controlled Substances Board, which has the authority to look at PDMP data to identify outliers or identify critically dangerous conduct or behaviors. So, that analysis from the CSB, the Controlled Substances Board Authority falls on DSPS [Department of Safety and Professional Services] [and] PDMP staff. It's a relatively new practice. Previously the PDMP data were not used in such a proactive way. It's a relatively new authority that the CSB has to use PDMP data to identify outlying prescribing practices (WI state employee).

These audits are directed by licensing boards that then decide how to investigate providers and what, if any, actions should be taken. Criteria for acceptable prescribing practices are set by the various licensing boards. The active involvement of licensing boards may explain the greater use of audits in Wisconsin's PDMP despite having fewer staff members.

Now that the PDMP use is beginning to become a best practice, or it's actually included in some of the prescribing board guidelines about best practices, taking into account the use of the PDMP is something that some of the boards are considering and are actually doing in identifying prescribers that are not following prescribing practices.

Just to give an example, the Board of Nursing referred some licensees, some prescribers who are high-volume prescribers of opioids,

for further investigation. They also want to have some targeted outreach to those that appear to be using the PDMP less than 50 percent of the time compared to the number of prescription orders they are writing. . . . So, the ability to do the audits was there and, in some cases, boards are setting different levels of criteria for the extent to which PDMP use comes into play when looking at dangerous conduct or behavior or making referrals for further investigation. (WI state employee)

Kentucky was reported to be the most proactive of the 3 and runs audits regularly to investigate providers and certain prescribing patterns.

P1: House Bill 333, that was passed, requires us to do quarterly reviews. So, we are looking at the data. So, we'll take, usually we'll work with a different licensure board, so we'll look at something in particular, like high MME values or, what are some other ones we've done?

P2: Pediatric prescribing. We get a lot of that. We get a lot of the dentists.

PI: And then we do a review, and based on that review, we might open up an investigation on a particular prescriber, or patient, or we might refer, if it's bad enough, we can refer it to law enforcement. If we feel like it's more of an administrative nature, then we'll refer to the licensure boards. So, there's a lot of discretion as to what we take, what we look at. Because, again, like they said, we can't confirm anything 100% by just doing the review. We're looking at it from a pharmacist's perspective (KY state employees).

As mentioned above, Kentucky PDMP can refer their investigations to law enforcement or licensing boards. They have a dedicated group of pharmacists who work within the PDMP to fill this "drug enforcement" function.

We also have the drug enforcement unit, and we have six pharmacist consultants. So, they are licensed pharmacists, but they are also law enforcement and they utilize the system, utilize KASPER daily. They take complaints about inappropriate prescribers and dispensers as well as looking at people who may be doctor shopping or going to multiple pharmacies or prescribers to get medications, controlled substances. So, they work very closely with the licensure boards and local law enforcement as well as state and federal. So, they are very much involved in a lot of these task forces. The US Attorney's Office right now has established task forces, and they are part of that, in seeking prosecutions for inappropriate prescribers (KY state employees).

Physician perceptions and use of PDMPs

The potential for the PDMP to have a deterrent effect on physicians' prescribing depends on how physicians view the PDMP, its purpose as a clinical tool or monitoring device, and their perceived responsibilities to their patients. Although states differed in the degree to which they monitored physicians' prescribing, perceptions of the PDMP and their effects on

prescribing did not vary much by state. Most physicians viewed the PDMP as a way of preventing patients from doctor shopping and misusing or diverting opioids.

Initially, [the PDMP] really was intended to stop doctor-shopping. It was almost that was the primary view of it. So, that we now will have this data available so that practitioners, pharmacists, and other authorized users, will be able to identify these people that are going from provider to provider to get controlled substances for abuse. Because, there was no way to track that. A doctor had no way of knowing, other than asking the patient, "Are you getting these from anybody else?" and, of course, the patient's not going to tell them the truth there. So, they had no way of doing it. So, that was really a major focus on it when it was first launched (KY state employees).

As seen above, the purpose of the PDMP to prevent doctor shopping assumes that many patients will lie to providers about their use. In cases in which patients are caught doctor shopping, doctors are not supposed to prescribe them more opioids in order to curb opioid misuse and diversion. However, how they should treat the patient is not clear.

I check everybody. Before I will prescribe for anybody, I go in and find out what else are they getting and who are they getting it from. And there's, I'm suspicious, but I'm willing to listen to a good tale. But I've caught quite a few people who were getting things from multiple places and I say, "Golly gee, I really want to help you but oh, we have this issue." "Oh no, not really." "Yes, you are." So, and there's a lot of, I'm not going to say older, but more veteran providers who I know don't know how to sign up for this, and they don't know it's required. And then it's too much trouble, and they try to delegate to checking other people. And I go, "No, really seriously. It's kind of fun. It's like a video game you can win." And you say, "I win. I caught them." So, it's not that much work. (WI Behavioral Health/Substance Misuse Treatment provider)

If patients do not reveal all the medications they have been prescribed or providers they have seen, this may indicate that they are seeking medications for diversion or for their own use, either for uncontrolled pain or because they have developed an opioid use disorder. However, few physicians reported using the information from the PDMP to guide a patient's treatment by assessing whether the patient has an opioid disorder or uncontrolled pain that could be treated without opioids.

This is in contrast to the way some pain specialists use the PDMP. Some pain specialists reported using the PDMP not just to identify patients to whom they should not prescribe because of multiple prescriptions or doctor shopping, but to understand their pain, their medication history specific to treatment of that pain, and how past opioid use may affect their reactions to other medications or techniques to control their pain.

- I: Okay, so based on the way that you practice, do you feel like [the PDMP] has impacted your ability to manage pain effectively.
- P: I think it has helped us in the sense that even if we're not prescribing controlled substances for a patient in a

given treatment plan, if we can look in the PDMP and see what they've been exposed to before, then that also gives us that history of what we may be dealing with from a pain perspective and starting to get into the basic science level of pain and what these opioids do within the brain at the end of the day. So, if they say that, "Well, I'm not on any opioids. I haven't been on it for 3 months or 6 months" but then we look in the PDMP and the, "You know what? A year ago, you were on 180 of OxyContin and you've been on it or were on it for a year." Well, now that gives us a different perspective where, "Okay, this is what we're dealing with. This is what they were accustomed to. This is how it may have affected their pain perception, pain pathway, so on and so forth." So, even in that scenario, it does hold some value where we can see what that history has been and what the patient may have intentionally or unintentionally omitted from their history (WI Pain Specialist).

Red flags are placed to alert providers to patients who have seen more than 1 provider or used more than 1 pharmacy for prescription opioids. These red flags are sent back to providers who prescribed substances to these individuals to alert them that they prescribed to a patient who has seen more than 1 provider. This can also lead to the sense that the PDMP is being used to monitor physicians, described below.

If patients are ER [Emergency Room] and doctor shopping, you'll see different providers. I don't know what the number is, but once you get more than a few, like maybe three or four, providers prescribing a narcotic or a controlled substance, it actually creates an alert tab on the, like when you open up the patient it says, "High alert. Multiple providers," and then it'll also say "Multiple pharmacies," then it also says, "High opioid use," or something like that.

It does get flagged in that system, and the prescription drug monitoring program will even send out. . .to the providers, or send out emails through it saying, "You prescribed to someone that's a high alert. . . ." (WI Emergency Department physician).

Effects on prescribing habits/practices

PDMPs were set up to reduce excessive prescribing of opioids and almost all key informants agree that the PDMPs have decreased opioid prescriptions in their states. However, many physicians argued that these changes do not reflect improved knowledge of pain management, improved patient outcomes, or increased referral to drug treatment programs for those who may need it.

I mean but I do think there are physicians who were, at least based on, you know, again I have opinions on how chronic pain should be managed, but were probably within the appropriate scope of practice but were quite worried about opioid – and are probably more worried about opioid prescribing now than they ever have been.

And so, what does that lead to? That leads to under prescribing for patients who need it. So again, I get worried about that monitoring, you know, and that the, the light being shined so excessively on opioid prescribing. . . And physicians being scared to provide opioids because they're scared about their licenses and their DEA and, and litigation and going to jail and all the other things. (CT Pain Management physician)

While Emergency Department [ED] doctors occasionally see patients who they believe are seeking drugs, some described usually prescribing only 3-days of medication even for serious injuries for which they anticipate that patients may require pain medication for a longer period. One physician argued that this practice requires patients to follow-up with primary care physicians or orthopedic surgeons.

I don't prescribe more than 3 days. Ever. Should I probably be looking it up more often [the PDMP]? Yes, of course, but sometimes I'm rushed and I'm just like, "Okay, we're just gonna do. . ." They broke a finger; they get three days. "Follow up with your primary care doctor if you need more," kind of thing. . . . Even if it's for something that they might need pain medicines for longer, like a broken bone that takes six weeks to heal, but they're supposed to follow up with an orthopedic surgeon, or their primary care doctor. It's kind of also my way of getting people to actually do what I want them to do by following up with another doctor, because I'm not gonna prescribe them more pain medication (WI, Emergency Department physician).

Some providers suggested that the pressure not to prescribe opioids had unintended negative consequences on patients who are not getting the follow-up care they need after surgery. In other cases, some primary care physicians described caring for patients who have been overprescribed opioids for many years.

The other thing that happens is that as a result of House Bill 1 in 2012 and then subsequent iterations by the legislature when they try to crack down on the opioid prescriptions is that many surgeons, for instance, are not doing follow-ups after surgery because they don't want to prescribe more than what they prescribed in the hospital. And so, they are saying to people, well, go back to your PCP [Primary Care Provider]. So, the PCP is stuck then with weaning the person off the opioid or continuing it or whatever. There's a lot of "patient dumping" going on. So, I hear from my nurse practitioners, I got this patient who's so-and-so age, elderly, has been on opioids for 25 years that still has back pain and now they're my patient. They are 80 years old, or they're 70 years old, or whatever. And I'm not gonna take them through a weaning process and so forth, but I'm now responsible in my prescribing (KY patient advocate).

According to key informants, some physicians engage in "patient dumping" which is not just discontinuing opioid prescriptions, but in many cases leads to a refusal to treat the patient. When a patient is a long-term user of opioids, many physicians will simply tell the patient that they are no longer able to prescribe opioids and will not work with the patient to treat their underlying conditions in other ways.

Unintended consequences

Key informants suggested that there were unintended consequences of the PDMPs including the misinterpretation or misuse of PDMP data for political ends. Another consequence suggested by key informants is the reluctance to prescribe opioids when appropriate, or to stop seeing or prescribing to patients who were inappropriately treated with opioid medications for long periods of time. These consequences were linked in some key informants' minds as state legislatures call for increased monitoring and control of physicians' prescribing patterns as the opioid crisis is attributed mainly or exclusively to overprescribing.

The other issue that we have. . . and it has come up the last couple of [State legislative] sessions. . . is that opponents will pull KASPER numbers in this broad brush, and not take into account the number of prescribers, let's say, and say, "Oh, well look at this huge increase in the number of prescription opioids that the NPs [Nurse Practitioners] have had from 2011 to 2015. Well, the number of NPs also dramatically increased during that time period and those numbers are in there, but if you don't bother to pay a lot of attention to it. The other thing that I'm told, and I'll use Clay County as an example because Clay County in eastern Kentucky is one of the counties that has one of the worst opioid problems and it is also the home county of the Senate president, Robert Stivers, so, it gets to be a really important county and he's so upset about what's happening in Clay County that this past session, I heard from reliable sources that if he had his way, he would have nobody prescribing opioids. I mean nobody, docs, nurses, dentists, optometrists, veterinarians, nobody. (KY patient advocate)

Political pressure may lead to misinterpretation of data, as the advocate above explains. Increasing rates of opioid prescribing may be due to more prescribers such as NPs moving into an area that may have been medically underserved before. Political pressure may also result from continued perceptions of an opioid crisis. However, the impulse to more tightly prescribe opioid prescribing may not solve the opioid problem and may cause additional problems as will be seen below.

Reducing opioid prescribing does not address the issue of people addicted to and misusing opioids. Many participants shared the opinion that the PDMP and new opioid prescribing recommendations have become a reason for doctors to avoid treating problematic patients while also avoiding being marked as someone who prescribes excessive amounts of opioids.

The challenge, or one of the challenges I've seen, is when we often-times do see these patients coming in from other clinics or primary care for that matter. I think too often the PDMP and the government is being blamed for why physicians can't, not won't, but can't, prescribe opioids. It's becoming an easy way out for the clinicians where they deflect having that difficult conversation to "It's somebody else's fault and I can't control it." (WI Pain Physician)

When patients are "dumped" in this way, they will likely have a physical dependency on opioids and will go through withdrawal if medications are abruptly stopped. As

some providers suggested, the person may have an underlying substance use disorder that cannot be treated by simply discontinuing the supply of opioids through refusing to prescribe more opioids.

- I: And with the PDMPs, have you seen any like increase or decrease in the amount of prescription opioids?
- P: I've seen a decrease. I'm catching fewer people with multiple prescribers but I'm getting more people coming in and demanding things from me because, "He cut me off." Yeah, well. And because for a lot of providers it's so black and white. "Oh, well, we're not supposed to be doing this anymore, so we aren't going to do it."

Yeah there are reasons why some people need to be on some things for a short amount of time. And cutting them off cold turkey is kind of cruel. Especially if somebody has been on opioid therapy for decades. Even if we know intellectually and scientifically, it's not doing them any good, it's still not compassionate to just cut them off and say, "Yeah, go get yourself some extra strength Tylenol." But a lot of, particularly the family practice providers, they were scared to do this in the first place and now that it's not as acceptable, they just say, "Oh, you're going to have to go someplace else." Well, we don't have a lot of pain clinics around to absorb all the people that the family care providers are throwing out the door. So, we end up with a lot of them here [in a substance abuse treatment clinic] in crisis going through withdrawal, not knowing what to do, never having their underlying issues really treated, just being, having been given opioids for years. Though we are now uncovering other addiction issues. We're uncovering depression, PTSD, all that stuff that used to be masked by the opioids. (WI, Behavioral Health/Substance misuse treatment provider)

As our participants almost universally agreed, there is a scarcity of substance use treatment and behavioral health providers nation-wide, and so many people who are cut off from long-term opioid use may not have access to treatment that can address their withdrawal symptoms, substance use disorders and other underlying mental health issues. In these cases, some patients may switch to street opioids, like heroin or fentanyl, or other kinds of substances like methamphetamine. Many harm reduction providers and first responders in Wisconsin and Kentucky noted an increase in heroin use as prescription drugs became harder to get.

I was there when KASPER was instituted or when it came online. It did make prescription opioids much harder to get on the street. They're still available to a certain extent, not like they were before the implementation of the KASPER program, but it's why those people who were addicted to opioid prescription pills went to heroin. And once again, that's an unfortunate side effect. (KY Harm Reduction employee)

- I: I know you mentioned some of these before, the most popular drugs in the street, but what are the most popular opioids on the street, brand names, street names?

- P: So, for us, it's heroin. We're seeing, obviously, a lot of fentanyl along with that. Our prescription pills, as far as opioids, has definitely gone down. So, we're not seeing like we used to the hydrocodone, the oxycodone, but it's definitely heroin.
- I: Okay, is there any reason why they're going more toward that?
- P: I think it's easier to get. I think we've done a good job of making the prescription pills harder to get, especially with a lot of prescription monitoring things that we do now. So, I believe pills are harder to get. So, heroin is just easier and cheaper (WI Police officer).

Discussion

Results from our study suggest that differences between state PDMPs are more nuanced than conceptualized in many previous studies.^{18,20,27,29} On paper, Connecticut's, Kentucky's and Wisconsin's PDMPs look very similar with mandatory registration and use by all providers. This reflects a broad trend toward mandated registration and use seen in states in the US over time and is likely to continue.³⁸ However, the states differ in the extent to which these mandates are implemented and enforced. These differences would be difficult to capture in a quantitative survey. Our qualitative interviews suggest that Connecticut is still mainly focused on provider compliance with registration and relies mostly on education to get providers to register with and use the PDMP. Kentucky and Wisconsin measure compliance ensuring both that prescribers are registered and that they query the PDMP prior to prescribing controlled substances. The states also differed in the extent to which physicians' prescribing practices are monitored by the PDMP and the involvement of state licensing boards and law enforcement. All 3 states provide prescribers with "report cards" in which their prescribing is compared to peers'. However, Wisconsin and Kentucky also conduct audits of the PDMP in search of high prescribers. Kentucky conducts these on a quarterly basis while Wisconsin conducts these when requested to do so. In both Kentucky and Wisconsin, high prescribers are reported to state licensing boards or law enforcement for further investigation and disciplinary action. Use of the PDMP by law enforcement also differs by state. Connecticut, unlike Kentucky and Wisconsin, is more restrictive in how law enforcement can access the PDMP, requiring a subpoena and a court order, while law enforcement can conduct investigations in Kentucky or Wisconsin in an active investigation without subpoena. Kentucky has a law enforcement unit within the PDMP. Thus, the 3 states vary significantly in their implementation and enforcement with Kentucky stricter than Wisconsin, which is stricter than Connecticut.

All 3 states have also taken steps to increase ease of use of the PDMP by incorporating the PDMP into some EHR systems. This has also been a trend in PDMP changes across the country, as research on the early implementation of PDMPs found that having to log in to a separate system to access the

PDMP was mentioned as a significant barrier to PDMP use by physicians.^{30,31,40-43} While all states also had interstate sharing systems, this capability was not utilized by the physicians and pharmacists in our study. PDMP data from other states are not integrated into a state's PDMP making the interface more difficult. In addition, algorithms may help to specify for which patients, and in which states a query should be run. The need for better interstate sharing was mentioned by state PDMP employees in previous qualitative studies.²⁹

Although the 3 states differ in the extent to which physician prescribing patterns are monitored, physicians' perceptions of the use of PDMPs were similar in all 3 states. The existence of the PDMP, mandated use, and physician report cards appear to act as a deterrent to opioid prescribing. While most participants concede that providers cannot be compared with others without more information about their specialty and particular patient loads, as indicated by at least 1 key informant, they understand that the peer reports will have a chilling effect on opioid prescribing. As 1 key informant stated, "It's okay if they are a little paranoid." This is consistent with qualitative research that found that 60% of physicians in Virginia felt that their prescribing practices were being monitored more closely after implementation of the PDMP.⁴⁴ Deterrence of opioid prescriptions was mentioned by key informants in all 3 states, in spite of differences in the extent to which the PDMP is shared with licensing boards and law enforcement, suggesting that peer report cards may indicate greater surveillance of physician behavior than actually is occurring and contribute the most to changes in prescribing patterns. This is consistent with some literature that has shown that physicians prescribe fewer opioids after PDMP implementation, particularly if these are accompanied by mandated use requirements.^{21,40,45} Other research, on the other hand, found that physicians and pharmacists would not be discouraged to prescribe or dispense opioids and that use of the PDMP both increased opioid quantities.^{46,47} Future quantitative research should explore the extent to which a state's proactive auditing or sending reports to licensing boards or law enforcement contributes to changes in opioid prescribing beyond what mandated PDMP check provide.

While changes in prescribing behaviors may help move physicians to prescribe in line with current guidelines, as seen in our results, it also may have the unintended consequence of doctors "dumping" patients with long-term opioid use, perhaps due to chronic pain. According to our key informants, PDMP must query rules also results in surgeons or ED doctors under-prescribing pain medications following surgery or accidents and sending them instead for follow-up care with PCPs, who often are uncomfortable prescribing opioids. Some patients who are dumped in this way may end up in reputable pain clinics where physicians try to find the root causes of their pain and different methods of treating it. As mentioned by substance use disorder treatment providers, some patients may end up in withdrawal and in substance use treatment. According to police and harm reduction providers, some of these patients may turn

to prescription or illicit opioids bought on the street, increasing their risks of overdose as many counterfeit prescription opioids and heroin are now cut with fentanyl. These results are consistent with research on the perceived unintended consequences of PDMPs which included the perception that pain patients would be undertreated and that under-prescribing could lead to street opioid use, including heroin.¹⁷ Future research should explore the unintended consequences of PDMPs by surveying chronic pain patients. Future research should also explore differences in how the PDMP affects physician opioid prescribing for ethnic and racial minority patients who may be seen as more drug seeking. Research has found that emergency physicians are less likely to prescribe opioids to Black, Hispanic and Asian patients than white patients.⁴⁸

Our results provide some support to research that has found that PDMPs increase use of heroin/fentanyl, although it is not clear from our data that more restrictive PDMPs may increase this tendency more.¹⁷ As mentioned, PDMPs, especially those that are more actively monitoring prescriber behavior, have a deterrent effect on prescribing opioids. First responders and harm reduction providers in Wisconsin and Kentucky pointed to the PDMP as reducing the amount of prescription opioids on the street and leading to increased heroin and fentanyl use and availability. However, this expressed sentiment must be interpreted with caution as Connecticut has also suffered from increased overdoses as a result of the flood of fentanyl into their drug markets.⁴⁹ While many researchers suggested that ultimately decreasing opioid prescription would prevent all opioid use disorders, including heroin and fentanyl, since most people with opioid use disorders were found to have begun by taking prescription opioids, recent studies have suggested other drug use trajectories.⁵⁰ People may initiate opioid use with heroin or fentanyl, particularly now that these drugs are easily accessed. Lowering the number of people who are prescribed and ultimately become dependent and may subsequently misuse prescription opioids is, in general, a positive outcome of the PDMP. However, this must be accompanied by expanded SUD treatment and compassionate care for long-term users of prescription opioids. These unintended consequences may be exacerbated by the COVID-19 pandemic as substance use has generally increased and substance use treatment facilities are filled to capacity as a result.⁵¹

The present project has a number of limitations. First, we include only data from key informants. Although our key informants represent a broader spectrum of professionals with different experiences of the PDMP than in previous qualitative papers on implementation and enforcement of PDMPs, the analysis for this paper did not include people who use heroin or prescription opioids nonmedically. Future research will analyze data from people who use heroin or prescription opioids. This will allow us to determine the extent to which people who were prescribed opioids had doctors refuse to continue to prescribe, whether this led some to pain specialists or treatment for substance use disorder, and whether they perceive a decrease in the

availability and increase in the price of prescription opioids since implementation of the PDMP. In addition, our paper did not consider the perspectives of chronic pain patients. Finally, the paper describes the experiences and perceptions of key informants of PDMPs in only 3 states, which may not represent PDMPs in other states. However, the 3 states in this study were purposively selected to represent diversity in terms of their PDMPs. Furthermore, states appear to be moving to more similar PDMPs over time.

In spite of these limitations, our results suggest the importance of more in-depth analyses of implementation and enforcement of PDMPs. Our results suggest significant differences in how mandated use rules are monitored or enforced among the states that may shape physicians' perceptions and prescribing practices. These may be variations in degree rather than kind but may help to explain the mixed results of research examining the effects of PDMPs on opioid prescription, overdose, and heroin and fentanyl use found in the literature. Differences in implementation and enforcement of the PDMP among states have not been well-studied and there is a need to expand this sort of research to other states with differing PDMPs and to continue this research as PDMPs change over time.

Author contributions


JDG is Principle Investigator of the project and was responsible for the design of the project, led data analysis and wrote the manuscript. EC was responsible for coordinating qualitative data coding, read and editing first drafts of the manuscript. MW is CT site PI of the project and helped in the conceptualization of the paper and its revision. CG was responsible for reviewing early drafts and secondary information on PDMPs. JW, AS, MM and JO were responsible for coding data and for reading and editing the manuscript.

Ethical approval

Ethical approval was obtained from the Institutional Review Board of the Medical College of Wisconsin. All participants provided written informed consent prior to participating in this project.

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