The Pennsylvania Prescription Drug Monitoring Program

Reducing the Misuse of Prescription Opioids

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In 2016, 4,642 Pennsylvanians died from a drug overdose and 85% of these deaths were due to an opioid overdose (U.S. Drug Enforcement Administration and University of Pittsburgh School of Pharmacy 2017). With a 37% increase in deaths from 2015, the Commonwealth's response to this epidemic has come from several fronts. One valuable resource has been the modernization and implementation of Pennsylvania's Prescription Drug Monitoring Program (PDMP). PDMPs are state-run programs that record dispensing of most controlled substances and provide this data to physicians and pharmacists (among others) to inform their practice about possible opioid use disorder by a given patient. This article discusses the role of Pennsylvania's PDMP in patient care and law enforcement to reduce opioid overdoses in the Commonwealth. Recent evidence is discussed that demonstrates the effectiveness of state-run PDMPs and their impact on opioid misuse and prescribing patterns. It is important to note that additional research into the effectiveness of PDMPs in preventing opioid-related morbidity and mortality is needed.

O pioid overdoses in the United States have evolved into a full-fledged public health and public safety crisis, associated with rising overdose death rates, detrimental social consequences, increased health- and safety-related risk, and high economic costs. In fact, overdose deaths have nearly tripled from 1999 to 2014 and continue to rise (Rudd et al. 2016). In 2015, it is estimated that over 52,000 overdose deaths occurred nationwide, with about two-thirds related to opioid use (Rudd et al. 2016). Pennsylvania is clearly at the epicenter of the epidemic, with the sixth highest overdose rate in the United States in 2015 (Rudd et al. 2016). In 2016, fatal overdoses rose by 37% in Pennsylvania, totaling 4,642 people, with opioids (prescription, heroin, fentanyl, fentanyl-related substances, nonprescription synthetics) found in 85% of overdose fatalities, and prescription opioids found in 25% of overdose fatalities (U.S. Drug Enforcement Administration and University of Pittsburgh School of Pharmacy 2017).

Nearly 3 million individuals in the United States are estimated to have an opioid use disorder involving prescription pain relievers or heroin (Bose et al. 2016). Opioid use disorders related to prescription pain medications are highest among adolescents and young adults, and approximately one-third of people 12 years and older who used drugs for the first time began with consuming a prescription drug nonmedically (Bose et al. 2016; U.S. Executive Office of the President of the United States of America 2011).

The role of prescription opioids in opioid use disorder and overdose lends itself to addressing prevention, intervention, and treatment efforts with prescribers and dispensers. Several key initiatives in Pennsylvania specific to prescribers and dispensers are underway (described elsewhere in this special issue), including development of an extensive series of prescribing guidelines by the Department of Drug and Alcohol Programs (DDAP) and the Pennsylvania Medical Society (PAMED); issuance of a standing order to Pennsylvania pharmacists to allow dispensing of naloxone to patients or third parties without a doctor's prescription; and Good Samaritan legislation that safeguards individuals administering naloxone to save a life. This article will discuss the evolution and implementation of prescription drug monitoring programs (PDMPs), both nationally and in Pennsylvania. PDMPs are state-run programs that collect information on patients who receive controlled substances (see below) dispensed by a pharmacy or other dispenser. Currently, all states have such programs. Missouri, the last state to join, does have a limited PDMP law on the books as of July 17, 2017, but the program has not yet been implemented.

Controlled Substances Monitored by the PDMP

PDMPs do not monitor all medications prescribed to a given individual, only those that are classified as controlled substances. The Controlled Substances Act (CSA), a federal drug policy that regulates the manufacture and distribution of controlled substances such as hallucinogens, narcotics, depressants, and stimulants, was enacted into law in 1970. The CSA categorizes drugs into five "Schedules" or classifications based on their potential for abuse, status in international treaties, and any medical benefits they may provide, in descending order, with Schedule I having the most potential harm (see Table 1).

The CSA was initiated to enable the United States to comply with the requirements of two international treaties. The 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances treaties set a system for classifying controlled substances in accordance with binding scientific and medical findings through the CSA, with two primary benefits. First, a schedule system makes it easier for state legislatures to enact criminal statutes by referring to the schedules rather than having to list all substances within the text of the law. Enforcement of the provisions of the CSA is a function of the Drug Enforcement Administration (DEA). Second, a schedule system also makes it easier for drugs to be added and removed from a schedule rather than having to change an entire drug law. Proceedings to add, delete, or change the schedule of a drug or other substance may be initiated by the Drug Enforcement Administration (DEA), the Federal Drug Administration (FDA), or by petition from any interested party, including the manufacturer

Table 1. Schedule of Controlled Substances	
SCHEDULE I	No currently accepted medical use; high abuse potential (e.g., LSD, Ecstasy, marijuana)
SCHEDULE II	Accepted medical uses, but high abuse potential leading to psychological or physical dependence (e.g., morphine, oxycodone, methadone)
SCHEDULE III	Less abuse potential than Schedule II drugs (e.g., codeine [in limited amounts], buprenorphine, amphetamines, anabolic steroids)
SCHEDULE IV	Lower abuse potential than above (e.g., alprazolam, diazepam)
SCHEDULE V	Preparations containing limited quantities of certain narcotics (e.g., codeine-containing cough syrups)
Source: U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division. Available at https://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm.	

of a drug, a medical society or association, a pharmacy association, a public interest group concerned with drug misuse, a state or local government agency, or an individual citizen.

As mentioned, the "drugs" monitored by a PDMP are controlled substances as defined by the CSA; however, PDMPs are state specific and the actual schedules monitored are determined by each individual program. The Pennsylvania Department of Health (DOH) administers the PDMP, and registration is mandatory for all prescribers and dispensers of Schedule II–V controlled substances.

A Brief History of the PDMP (1939–current)

The first PDMP established in the United States was in California in 1939, followed by the Hawaii program in 1943. Between 1943 and 1990, seven other programs were established: Illinois (1961), Idaho (1967), Pennsylvania (1972), New York (1972), Rhode Island (1978), Texas (1981), and Michigan (1988). Early programs collected information on drugs currently equivalent to Schedule II drugs only, and all used some type of state-issued serialized prescription forms. Multipage forms allowed one copy of the prescription to be sent to the PDMP monthly for data entry, while the pharmacy, and in most cases the prescriber, each kept a copy. Reports were only provided to law enforcement, regulatory agencies, or professional licensing agencies. During the 1990s, seven additional states operationalized PDMPs. During this time frame, several improvements occurred. First, Oklahoma (1990), followed by Hawaii and Massachusetts (1992) became the first states to require electronic transmission of data, which increased accuracy and timeliness of submissions. Second, several years after its establishment, the Nevada (1997) program began to provide data to prescribers and pharmacists by fax, and eventually via an online system.

Since 2000, 49 states have either established, updated, or maintained PDMPs. Not surprisingly, programs during this time saw an increased use of electronic submission protocols and reports. Since these programs are established and administered at the state level, there are differences between states, including housing of the program, funding, drug schedules collected, reporting requirements, collection of data for identified nonscheduled drugs, and which stakeholders have access to PDMP data. Overall, current programs typically collect data on all schedules of controlled substances; report data to a centralized database within 1–3 days; and provide reports to physicians, pharmacists, law enforcement, licensing boards, and depending on the state, other appropriate groups. As time passes, more and more states are also requiring

some form of mandatory use of the PDMP, most often prior to prescribing or dispensing opioids and other controlled substances. Updated information on many characteristics of PDMPs is available at the website of the National Alliance for Model State Drug Laws (NAMSDL).

As one reads the history of PDMPs, it appears that Pennsylvania was a pioneer in the area with a program established in 1972. However, this observation is somewhat deceiving. Although the other early implementers gradually increased the numbers of drugs reported and improved data access to health care practitioners, Pennsylvania lagged behind for many years. The following section details the history and evolution of the PDMP in the Commonwealth.

The Evolution of the Pennsylvania PDMP (1972–present)

Pennsylvania passed Title 28 PA Consolidated Statute, Chapter 25, Subchapter A, Section 25.131 in 1972 to improve the ability of law enforcement to use controlled substance data. The "original" PDMP program required pharmacies to report to the Office of the Attorney General (OAG) on triplicate paper forms to eight different regional offices around the Commonwealth. In 2002, the OAG operationalized an electronic prescription filing program for Schedule II controlled substances. Although efficiency of data collection was improved with electronic filing, deficiencies were apparent: only Schedule II drugs were monitored, data was submitted monthly, and reports could only be queried by law enforcement and were not available to physicians and pharmacists. As other state programs were introduced and existing programs were updated, by 2012, Pennsylvania was the only state that collected only Schedule II data monthly.

Recognizing the need to modernize, PDMP reform began in the 2011–12 legislative session with the introduction of HB 1651, sponsored by Representative Gene DiGirolamo (R-Bucks). The bill proposed the establishment of the Pharmaceutical Accountability Monitoring System (PAMS) to replace the program established in 1972. This legislation was referred to the Committee on Human Services on August 6, 2011, and was laid on the table on February 6, 2012, without a floor vote. A second attempt to form the PAMS occurred during the 2012–13 legislative session. This attempt (HB 317) was also introduced by Representative DiGirolamo and was also laid on the table on December 8, 2013, without a floor vote.

The third attempt by the House to pass PAMS legislation took the form of HB 1694, sponsored by Representative Matt Baker (R-Tioga). The bill was introduced during the 2013–14 legislative session. Third consideration and final passage of the bill occurred on October 21, 2013, and the bill was sent to

the Senate. The Senate version of a PDMP took the form of SB 1180 sponsored by Senator Pat Vance (R-Cumberland). This bill renamed the PDMP as the Achieving Better Care by Monitoring All Prescriptions (ABC-MAP) Act. The bill passed and was signed in the Senate on October 16, 2014, signed in the House on October 20, 2014, and signed by Governor Corbett on October 27, 2014. ABC-MAP subsequently became Act 191, which currently defines the parameters of the Pennsylvania PDMP. The program is housed in the Department of Health and began data collection in August 2016.

The Parameters of the PDMP (Act 191)

The PDMP monitors Schedule II–V controlled substances. Medication-assisted treatment (MAT) providers are not required to submit data to the Pennsylvania PDMP system. The two primary users of the PDMP system are the prescriber (a person who is licensed, registered, or otherwise lawfully authorized to distribute, dispense, or administer a controlled substance, other drug, or device in the course of professional practice or research in this Commonwealth), and the dispenser (a person licensed to dispense in this Commonwealth, including mail-order and internet sales of pharmaceuticals). Both prescribers and dispensers are required to register and query the PDMP before prescribing or dispensing an opioid or benzodiazepine drug product under a set of predefined conditions available on the PDMP website.

The PDMP is continually updated and improved to give prescribers and dispensers more advanced tools to help practice and streamline workflow. For example, in September 2017 the PDMP launched an initiative to integrate the PDMP system with the electronic health records (EHRs) and pharmacy management systems of all eligible health care entities in Pennsylvania. According to the Department of Health (DOH) website, "The goal is to minimize any workflow disruption by providing near-instant and seamless access to critical prescription history information to both prescribers and pharmacists" (www .health.pa.gov). As an additional incentive, DOH is covering the subscription fees associated with using this service for every health care entity in Pennsylvania that elects to connect its health IT system to the PDMP until August 31, 2019. Any health care entity in Pennsylvania that is legally authorized to prescribe, administer, or dispense controlled substances is eligible to apply for integration. Applications for integration are available at the above website, and two health care entities have been integrated thus far.

Additionally, as of January 2018, the Pennsylvania Prescription Drug Monitoring Program is sharing data with 16 other states and D.C., helping prescribers and pharmacists to obtain a more complete picture of their

patients' controlled substance prescription histories, regardless of where they filled their prescriptions. However, challenges in obtaining an accurate picture of patient histories still remain. Hawk et al. found that, "although the PDMP can accurately reflect the history of prescription opioids of a patient, the ability to accurately differentiate between the phenotype of aberrant opioid use or opioid use disorder and that of untreated or undertreated pain based on PDMP information alone, particularly among patients who are uninsured or do not have a primary care provider, remains a challenge" (2017).

Evidence of PDMP Effectiveness

Nationally, the PDMP has been shown to be effective in addressing opioid use disorder, reducing overdoses, and minimizing costs. First, the PDMP can reduce the volume of opioids accessible. A 30% reduction in the rate of Schedule II opioid prescriptions was observed in a review of 24 states that implemented statewide use of their PDMPs (Gugelmann and Perrone 2011). Second, the PDMP can increase early intervention strategies and/or referral of persons with possible opioid use disorder to treatment. A survey of Rhode Island and Connecticut prescribers revealed that prescribers who conducted PDMP queries were more likely to follow up with patients suspected of harmful prescription drug use with drug screens or referrals to treatment (Green et al. 2012). Third, PDMPs are associated with reduced overdose deaths. A 2016 national survey analyzed statistics for a one-year period, in which 49 states (all states but Missouri) had implemented PDMPs. State implementation of PDMP programs was associated with an average reduction of 1.12 opioid-related overdose deaths per 100,000 in the year after implementation of the PDMP (Patrick et al. 2016).

As hopeful as these results are, Hawk et al. caution physicians against relying too much on the PDMP when making crucial decisions about patient care. They say, "despite a small body of work suggesting a positive benefit of PDMPs, multiple challenges limit the ability of PDMPs to exert their full potential including robustness, ease of navigation and integration of electronic medical records, further research into how data associated with PDMPs should influence clinical care, and changing physician attitudes regarding PDMP utilization" (2017).

In Pennsylvania, analysis of overdose death data from 2014 to 2016 indicated that prescription opioids were present in approximately 25% of overdose deaths during those years. In 2016, over half of all overdose deaths were attributed to fentanyl and fentanyl-related substances, which experienced a 130% increase from 2015 to 2016. It is important to note that fentanyl can

be prescribed, but it is often synthesized and obtained illicitly. Furthermore, deaths related to prescription opioids experienced the smallest percent increase (3% from 2015 to 2016) compared to other drug categories. In fact, in 2016, the percentage of overdose deaths that were attributed to prescription opioids remained relatively stable throughout the year.

In the first quarter of 2016, prescription opioids were present in 31.3% of toxicology reports. In the second quarter of 2016, the percentage of prescription opioids fell to 27.4% of toxicology reports, followed by 27.5% in the third quarter of 2016. In the last quarter of 2016, prescription opioids were present in 22.5% of toxicology reports. The PDMP was introduced in August 2016, which may have contributed to the decrease in prescription opioid-related deaths in Q4 of 2016. It is important to note that these data are preliminary, and future studies should be conducted as more data becomes available.

One year into implementation of the updated PDMP, about 97,000 users have registered as of January 2018. The program's database has averaged approximately 53,000 searches on a weekday, and 9,000 searches on a weekend. As of September 2017, this utilization has decreased the number of patients who went to 5+ prescribers and 5+ dispenser/pharmacies in three months for Schedule II drugs by 89%. The number of youth that received prescriptions for painkillers with a morphine milligram equivalent greater than 100 mg per day has been reduced to 46% as of September 2017 (Communication with PA DOH PDMP office).

Facilitating Effective Use of the PDMP to Improve Patient Care

A provider can use the PDMP to improve patient care by discussing a patient's prescriptions to make sure he/she is aware of how opioids are used in pain management and the risks and harms associated with therapy; engaging a patient in a discussion about when it would be appropriate to taper off of opioids or move to a lower dosage; monitoring total morphine milligram equivalents/day dosage of all current opioids; monitoring for signs and evidence of misuse and/or risky behavior for an early intervention; referring a patient to substance or opioid use disorder treatment, if necessary; avoiding any potentially harmful drug-drug interactions (e.g., benzodiazepines); and discussing alternative pain management strategies before referring a patient to substance use disorder treatment.

The PDMP provides an infrastructure to improve patient care; however, ongoing training and technical assistance are crucial to its use in the prescriber/dispenser workflow. To address this, the Department of Health (DOH)

has developed a state-of-the-art educational system to support practitioner use of the Pennsylvania PDMP to promote optimal participation and use by all providers and prescribers within the state. The educational system contains seven different modalities that touch on various aspects of the PDMP, including: importance to population health, workflow and clinical decisions, optimizing pain management, appropriate opioid prescribing, SUD treatment, Screening–Brief Intervention–Referral to Treatment (SBIRT), and opioid tapering.

In addition, materials and delivery of training for health care systems that address practices to build a culture of change around prescriber use of the PDMP have been created. The training consists of a cultural change assessment to aid health care systems in identifying and overcoming organizational barriers to effective implementation of the PDMP, followed by ongoing technical assistance to implement the PDMP after the assessment for PDMP implementation readiness. Finally, some hospital systems within Pennsylvania have created peer-to-peer physician mentoring programs to improve opioid prescribing patterns.

The PDMP also provides valuable information to raise community awareness and to increase motivation to change prescribing practices. Leveraging local opioid overdose prevention coalitions, efforts are underway to engage the prescribers/dispensers as well as the persons receiving prescriptions. Prescriber/dispenser engagement is useful in disseminating the resources described in the paragraph above. At the public level, education revolves around teaching the basics of the PDMP, how and why it is used, how doctor's appointments may change from the patient perspective, how pharmacy visits may change from the patient perspective, and other key information to ensure a smooth transition for patients.

Role of the PDMP in Law Enforcement

Law enforcement's effective use of PDMP data facilitates identification and remediation of prescribers operating outside the scope of medical practice, as well as "doctor-shopping" patients; as such, PDMP use by law enforcement can have a significant impact on the availability of diverted prescription drugs subsequently funneled into the illicit drug market. Law enforcement analysis of PDMP data occurs during an active investigation of a suspected rogue practitioner. Identifying patterns of prescribing outside the norm of a physician's specialty, geographic area, or patient population base can be used in conjunction with traditional law enforcement techniques and other sources of information to determine the nature of criminal activity, if present.

Analysis of PDMP data at the macro, de-identified level by law enforcement allows for geospatial analysis regionally to identify prescribing levels based on population density, drug type, etc. Also, combining data sources, such as prescription opioid prescribing rates, with prescription opioid–related overdose deaths, contributes to a greater understanding of the impact of diverted pharmaceutical availability that can then be leveraged into decisions regarding law enforcement strategies, multidisciplinary resource allocation, and implementation of public health interventions.

Future Directions

With the enactment of Pennsylvania's Medical Cannabis Law (Act 16), the PDMP program faces another challenge—namely, whether a query of the PDMP should also provide medical cannabis products being used by the patient. It would be beneficial to the purpose of the PDMP (improved patient care and aiding law enforcement) for practitioners and law enforcement to obtain data not only on CII–CV substances, but also on cannabis products when querying the PDMP. Several obstacles exist to integration of the databases. The PDMP legislation in Pennsylvania requires submission of data on controlled drugs classified as CII, CIII, CIV, and CV. Despite passage of medical cannabis legislation in 29 states, dry leaf products and dosage forms produced from cannabis remain classified by the DEA as CI drugs (no accepted medical use). Therefore, according to Pennsylvania legislation, the Department of Health cannot directly include dispensing of cannabis products in the PDMP, since its classification is excluded from the legislation. The PDMP database and process already exist, and those for the medical cannabis registry are still being written.

At the current time, there are no plans to directly integrate these databases so that an inquiry into either registry will produce data from both. As a partial solution, the medical cannabis legislation does require prescribers in Pennsylvania to query the PDMP prior to recommending medical cannabis to a patient. Interestingly, Pennsylvania is not alone in this emerging dilemma. Of currently operational medical cannabis programs, only two (Connecticut and New York) provide medical cannabis information upon a query of the PDMP. They have done this by providing each dispensary and each cannabis product with unique identification numbers (similar to DEA numbers and NDC product identification numbers) that can be entered into the appropriate fields of a PDMP submission. When cannabis products are dispensed, dispensaries submit these identification numbers and patient information directly to the PDMP, and these products then appear on the PDMP report. In addition,

according to available information, the relatively new medical cannabis program in Ohio plans to integrate information from cannabis dispensaries and pharmacies directly into one report when the program begins. Of the remaining states permitting medical cannabis, only five have some partial integration like Pennsylvania. In all others, there is no linkage of the databases, nor requirements for prescribers to query the cannabis registry when prescribing controlled substances.

Conclusion

The PDMP continues to grow to meet the needs surrounding opioid prescribing and dispensing. First, the PDMP office is currently sharing data with 16 other states and D.C. for prescribers and dispensers to get a more complete picture of a patient's controlled substance use. Second, the PDMP office has begun to integrate the data system with electronic medical records, streamlining the data entry and checking processes. Third, with the data obtained, it may be possible to identify potential risk factors based on number of prescribers or pharmacies, overlapping prescriptions, morphine equivalency, and other patient health history information. As stated earlier, further research is needed to determine the effectiveness of PDMPs in evaluating patient histories and preventing death by overdose, and challenges still remain in the effective use of PDMPs. Hawk et al. stress "the importance of using screening, good history taking, clinician impression, and electronic medical records, in addition to using the PDMP to identify patients with opioid use disorder" (2017).

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