Prescription Drug Monitoring Programs

Kevin L. Zacharoff, MD, FACIP, FACPE, FAAP
Disclosures

- Unrestricted educational grant from Zogenix Pharmaceuticals
- Numerous National Institutes of Health research grants
Learning Objectives

- Discuss the definition and history of Prescription Drug Monitoring Programs (PDMPs) in the US
- Assess the role of PDMPs in safe and effective pain management
- Clarify the intention of PDMPs in clinical practice
- Discuss the demonstrated efficacy of PDMPs to date
Let’s Start Here
2011

- Epidemic: Responding to America’s Prescription Drug Abuse Crisis
  - “PDMPs aim to detect and prevent the diversion and abuse of prescription drugs at the retail level, where no other automated information collection system exists, and to allow for the collection and analysis of prescription data more efficiently than states without such a program can accomplish”

- “PDMPs can and should serve a multitude of functions, including: assisting in patient care, providing early warning of drug abuse epidemics (especially when combined with other data), evaluating interventions, and investigating drug diversion and insurance fraud*”

* PDMP data cannot be used as evidence in court
The 4 Pillars of the White House Plan

- Education
- Tracking and Monitoring
- Disposal
- Enforcement
What is a PDMP?

- A PDMP is a state-wide electronic database that gathers information from pharmacies on dispensed prescriptions for controlled substances
  - Most states that permit practitioners to dispense also require them to submit prescription information to the PDMP
- Prescription data are made available on request from end users and sometimes distributed via unsolicited reports

Who Gets the Reports?

- States vary widely in which categories of users are permitted to request and receive prescription history reports and under what conditions.
Who Else?

Additional recipients of data may also include:

- Licensing boards
- Law enforcement/drug control agencies
- Medical examiners
- Drug courts
- Criminal diversion programs
- Addiction treatment programs
- Public and private third-party payers
- Other public health and safety agencies

History

■ By 1989, 9 PDMPs had been established
  — These programs collected information only about Schedule II medications
  — All of these 9 programs relied on state-issued multipage prescription forms
  — Reports were provided to law enforcement and regulatory/licensing agencies

■ The Nevada PDMP, created in 1997, signaled a change, and started to provide data to prescribers and pharmacists (by fax)
History

- In 2001, Nevada develops an online system for reporting
- Some studies showed that PDMPs had significant impact
  
- Others reported that the multi-page prescription forms had a “chilling effect” on legitimate prescribing

My Personal Experience
Back to PDMPS

- By 2001, 16 states had passed legislation authorizing the creation of a PDMP
  - Remember, state-run programs (with or without Federal funding)
- By 2012, 49 states had passed legislation for PDMPs
  - 41 states had an operating PDMP
- August 27th, 2013 New York State mandates use of the PDMP
History

As of January 2013

- 49 states and 1 territory had passed legislation authorizing a PDMP
- 43 states had an operating PDMP
Let’s Look Under the Microscope
NYS: I-STOP/PMP

- Internet System for Tracking Over-Prescribing

  - Effective August 27th, 2013, most prescribers are required to consult the Prescription Monitoring Program (PMP) Registry when writing prescriptions for Schedule II, III, and IV controlled substances.
  - The registry provides practitioners with direct, secure access to view dispensed controlled substance prescription histories for their patients.
  - The PMP is available 24 hours a day/7 days a week via an application on the Health Commerce System (HCS) at https://commerce.health.state.ny.us.
  - Reports include all controlled substances that were dispensed in New York State and reported by the pharmacy/dispenser for the past 6 months.
  - This information will allow practitioners to better evaluate their patients’ treatment with controlled substances and determine whether there may be abuse or nonmedical use.
I-STOP FAQs

▪ What is the purpose of the PDMP?
  — Provides practitioners and pharmacists with direct, secure access to view their patients’ recent controlled substance prescription history to help them better evaluate a patient’s treatment as it pertains to controlled substance prescribing and dispensing

▪ What are the intended benefits?
  — Better understanding of controlled substance use
  — Quick, confidential online report
  — Availability (24/7)
  — Information based on data from almost 5,000 pharmacies
  — Free
I-STOP FAQs

▪ Who can access the PDMP?
  — Any licensed prescriber in NYS, excluding veterinarians
  — Pharmacists

▪ If a 5-day supply of a controlled substance is prescribed from an EMERGENCY DEPARTMENT in a hospital, do I need to consult the PDMP?
  — No

▪ If a 5-day supply of a controlled substance is prescribed from an office, surgi-center, urgent care facility, dental office, or clinic, do I need to consult?
  — YES
I-STOP FAQs

- What if the power goes out? Can I still write the prescription for a 5-day supply?
  — Yes

- If the power does go out, am I required to document in the patient’s chart that I was unable to consult the PDMP?
  — Yes
I-STOP FAQs

- What are the penalties if I willfully do not consult the PMP Registry when I prescribe a Schedule II, III, or IV?
  - There are no specific penalties attached to failing to comply with I-STOP
    - However, a violation of the provisions of this law is the same penalty as for any violation of the Public Health Law

- Can I designate someone else to do this. . . .???
  - YES
More About the Last “Yes”…

- Designees for practitioners:
  - The designee, if unlicensed, will need to work with the HCS coordinator from their facility, or prescribing practitioner, to establish their own HCS account.
  - After the designee obtains an HCS account user ID, the practitioner will need to log into the HCS, open the PDMP application, and click on the Designation tab.
  - On the designation screen, the practitioner will enter the HCS user ID of the individual that will be performing the look up on their behalf as a designee.
I-STOP FAQs

- Can I share the results of the report with my patient?
  - Yes
    - Based on your judgment

- Are refills and partially-filled prescriptions listed in the report?
  - Yes

- If I have patients who receive Schedule II prescriptions which require a new prescription with each fill. Do I have to consult the PMP for the same patient each month when writing the same prescription?
  - Yes
I-STOP FAQs

- Will there be a distinction in the report between immediate-release/short-acting and extended-release/long-acting medications?
  - No
    - Just the drug and strength
Let’s Get Something Straight

- PDMPs are tools that can potentially help track how medications are being prescribed and dispensed
  - They are, at best, one tool in the toolbox
Other Responsibilities

Don’t Be Scammed by a Drug Abuser

• Your responsibilities:
  • Legal and ethical
  • Professional
  • Personal
• Look for: unusual behavior, assertiveness, poor appearance, requests for specific drug, etc...

Office of Diversion Control, Drug Enforcement Administration.
CAREFUL!

You have to watch what you say....
Terminology

▪ What does the term “drug seeking” mean to you?
  — Sometimes there is confusion about the definitions
    ▪ Going to different multiple providers to get opioids?
    ▪ Inconsistency in pain and/or medical history?
    ▪ Asking for an early refill?
      — Lost or stolen meds
    ▪ Addiction is present?
    ▪ Substance/drug abuse is present?

▪ Is there anyone here who doesn’t think this has a negative undertone?

“Drug Seeking”

- When you use the term, are you referring to any or all of these?
  - The patient is addicted
  - The patient states the pain is unbearable
  - The patient is lying
  - The pain is undertreated
  - The patient is exaggerating
  - The patient is upset
  - The patient is manipulative
  - The patient is dependent or tolerant

The American Academy of Family Physicians on “Drug Seeking”

- Systematic approach
  - Involve the entire team—eg, office staff, family members
  - Recognize suspicious behavior
  - Obtain a thorough history
  - Consistency in the physical examination
  - Conduct appropriate tests—eg, urine screens
  - Use nonpharmacological treatments
  - Proceed cautiously

## Terminology

### Doctor shopping

*From Wikipedia, the free encyclopedia*

This article **possibly contains original research**. Please improve it by verifying the claims made and adding inline citations. Statements consisting only of original research should be removed. *(September 2007)*

This article **needs additional citations for verification**. Please help improve this article by adding citations to reliable sources. Unsourced material may be challenged and removed. *(September 2013)*

**Doctor shopping** or **double doctoring** refers to the practice of a patient requesting care from multiple physicians, often simultaneously, without making efforts to coordinate care or informing the physicians of the multiple caregivers. This usually stems from a patient's addiction to, or reliance on, certain prescription drugs or other medical treatment. Usually a patient will be treated by their regular physician and be prescribed a drug that is necessary for the legitimate treatment of their current medical condition. Some patients will then actively seek out other physicians to obtain more of the same medication, often by faking or exaggerating the extent of their true condition, in order to feed their addiction to that drug.

### What are Doctor Shopping Laws?

The term "doctor shopping" has traditionally referred to a patient obtaining controlled substances from multiple health care practitioners without the prescribers' knowledge of the other prescriptions. Almost all states have a "general" fraud statute that adopts verbatim or with slight alteration the provision in the Uniform Narcotic Drug Act of 1932 or the Uniform Controlled Substances Act of 1970. These statutes prohibit obtaining drugs, including through "doctor shopping," by any or all of the following means: fraud, deceit, misrepresentation, subterfuge, or concealment of material fact.

This resource distinguishes between general statutes and laws categorized as "specific" doctor shopping laws. Specific doctor shopping laws prohibit patients from withholding from any health care practitioner that they have received either *any* controlled substance or prescription order from another practitioner, or the *same* controlled substance or one of similar therapeutic use within a specified time interval or at any time previously.

### On this Page

- What are Doctor Shopping Laws?
- States with Doctor Shopping Laws
- Features of Doctor Shopping Laws by State
“Doctor Shopping”

“Doctor Shopping” (cont’d)

▪ One NIH-funded study states that “nearly 2% of all US opioid prescriptions, totaling an estimated 4.3 million prescriptions each year are purchased by patients presumed to be ‘doctor shoppers’”¹
  — Estimated that 1 out of every 143 patients is a “doctor shopper”
  — “The US Department of Justice took action to try to curtail the problem by making federal assistance available in 2002 for the computer-based prescription monitoring programs (PMPs) that collect data from pharmacies regarding dispensed prescriptions from certain drugs, including all schedule II drugs and several others. But those programs have not caught on with physicians, and currently only Kentucky and West Virginia legally require prescribers to access patients’ prescription histories in the databases before prescribing certain drugs.”

“Doctor Shopping” (cont’d)

“One of the problems of the PMP is it does require jumping through some hoops, such as password creation, and then looking up a prescription history, and that can take a significant amount of time and effort. My primary care provider, for instance, has 3000 patients, and if he were to use PMPs for even a 10th of those patients, that would be a lot of additional work in the scope of the traditional 15-minute appointment”
Let’s Zoom Back Out
Effectiveness of PDMPs

- Measured in terms of impact:
  - Use of prescribed controlled substances
  - Decreased rates of diversion and other aberrant behaviors
  - Improved health outcomes

- Factors that maximize effectiveness include:
  - Technological feasibility
  - Completeness of data set
  - Expeditiousness of analysis
  - Availability of data in a timely manner
  - Data presentation in format that is user-friendly
Uniformity!!! or Uniformity???
Variability Exists

- Currently there is variability between PDMPs in different states:
  - Data fields
  - Data formats
  - Comprehensiveness of data
  - Comparability across states
  - Ease of integration with other data
    (e.g., Medicaid, Indian Health Service, VA, and DoD)
Utilization Problems Exist\(^1\)

- Scarce resources for PDMPs and prescriber education limit the reach of efforts to increase utilization

- Lack of program resources to:
  - Develop an online automated response system
  - Reduce the reporting interval
  - Increase the timeliness of data
  - Provide decent educational efforts, and what type of education would be most efficacious

What about Resources?

- Mandated use requires:
  - Staff time
  - Resources
  - Legislative and regulatory consensus
  - Time
  - Money
PDMP Facts

The Machine is Definitely in Place
The abuse of prescription drugs is a serious public health and public safety problem

- In 2009, the number of first-time, nonmedical users of psychotherapeutics (prescription opioid pain relievers, tranquilizers, sedatives, and stimulants) was similar to the number of first-time marijuana users.
- The 2010 Monitoring the Future study—a national survey on youth drug use—found that 6 of the top 10 substances used by 12th graders were pharmaceuticals.
- Between 1997 and 2007, treatment admissions for prescription pain medications increased more than 4-fold.
- The number of emergency room visits involving misuse or abuse of pharmaceuticals doubled.
- In 17 states and the District of Columbia, drug-induced deaths are now the leading cause of injury death.
Are PDMPs Effective?

- PDMPs may be effective
  - Some studies show PDMPs are effective when fully utilized
  - A study in 2010\(^1\) study found that when PDMP data were used in an Emergency Department:
    - 41% of cases had altered prescribing after the clinician reviewed PDMP data
    - 61% of the patients receiving fewer or no opioid pain medications than had been originally planned by the physician prior to reviewing the PDMP data
    - 39% receiving more opioid medication than previously planned because the physician was able to confirm the patient did not have a recent history of controlled substance use

Who Typically Uses a PDMP?

- Survey in Oregon¹
  - Clinicians in emergency medicine, primary care, and pain/addiction specialties were the largest number of registrants
    - Many frequent prescribers were not registered to use the PDMP
  - Among users, 95% reported accessing the PDMP when they suspected a patient of abuse or diversion
    - Fewer than half would check it for every new patient or every time they prescribe
  - Nearly all users reported that they discuss worrisome PDMP data with patients
  - 54% reported making mental health/substance abuse referrals
  - 36% reported sometimes discharging patients from the practice
  - Clinicians reported frequent patient denial or anger

- More research needs to be done

Who Typically Uses a PDMP

- Same authors, different paper

  “Little is still known about the ways in which they are incorporated into workflow and clinical decision making, what barriers continue to exist, and how clinicians are sharing PDMP results with their patients”

  “Routines for accessing PDMP data and how clinicians respond to it vary widely. As PDMP use becomes more widespread, it will be important to understand what approaches are most effective for identifying and addressing unsafe medication use”

The Jury is Still Out

“If the full benefits of PDMPs are to be realized, we must have fully operational, interoperable PDMPs in every state, and health care providers must incorporate PDMP data into everyday clinical practice”

- Kerlikowske

EDITORIALS

Prescription Drug Monitoring Programs—Lack of Effectiveness or a Call to Action?
Conclusions