The Promises and Perils of Prescription Drug Monitoring

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Overview

1. Introduction
2. Prescription Drug Monitoring and the Opioid Crisis
3. Case studies
   ▪ Qualitative Study of Stakeholder Perspectives
   ▪ Social Listening Study of Reddit Users
   ▪ Secondary Administrative Data Analysis
4. Implications for Equity and Vulnerable Populations
Public Health Surveillance Context

- Complex history
  - Essential tool for health interventions
    - Tool of social control (abortion, STIs HIV)
  - Crisis-driven, fragmented regulation
  - Uneven application (race, class)
  - Evolving doctrine and norms on patient privacy, ethics, confidentiality, medical paternalism (e.g. dual loyalty)
PDMPs as Opioid Crisis Response

- Originally designed by, and for law enforcement
- Billions in federal, state funding
- Heterogeneity in design, legal authority, scope of registration and use mandates, and other regulatory components
- **Key element in opioid crisis response**

PDMP: What Data Are Collected?

- Outpatient prescriptions and dispensing, no consent
  - Name
  - Date of birth
  - Address
  - Gender
  - Race/ethnicity
  - Prescriber ID, Pharmacy ID (may be single ID for multiple providers)
  - Drug prescribed/dispensed (dosage, quantity, etc.)
“Big data” algorithms generate “red flags,” used as leads for investigations
  - 39 States allow such use

Providers: law enforcement, medical boards, regulators, public health authorities

Patients: law enforcement, regulators, public health authorities
Some systems generate reports to prescribers on how their practices compare to others.

- Mandate to consult for all schedule II-III prescriptions (e.g. MA)
- Mandate to consult for all new patients (e.g. MA)
- Training mandate for law enforcement (e.g. MA)
- No training required for prescribers or pharmacists on how to use data

Source: Drug Control Program, MA DPH
Mainstream PMP Critiques

- Seldom consulted systematically by prescribers, pharmacists
- Lack of interoperability among states
- Clunky, not user-friendly
- Takes too much time, unfunded mandate
- Not part of HIT infrastructure, EMR
- Not integrated with substance use treatment data (42 CFR Part 2 firewall)
Critical Public Health Perspective

- Not informed by decision-support science: little/no guidance or training on *how* to use PMP data to reduce patient risk
- Possible chilling effect on pain management
- Possible chilling effect on help-seeking
- Scope limited to drugs that no longer primary drivers of overdose
- Equity concerns
- Privacy concerns
Office-based buprenorphine or methadone (for pain/SUD, but not OTPs)

42 CFR Part 2 is under attack
- Hormone therapy (testosterone, estrogen)
- Benzodiazepines (mental health)
- Amphetamines (mental health)

Some patient groups (e.g. SUD, mental health, LGBTQ) especially at risk for negative interactions, trauma related to health care
Existing Literature

- Evidence of public health impact uncertain (Beletsky, 2018; Fink et al., 2018)
- Challenges in ecological observation, given concurrent intervention environment (Surgeon General, 2016)
- Textual analysis of authorizing legislation (Davis et al., 2015)
- Limited qualitative work focused on providers (Green et al., 2013; Hildebran et al., 2014), administrators (Katz et al., 2008)
  - Gap in data on drug user, other stakeholder perspectives and experiences
Goals:

1. Understand scope of stakeholder experiences and perspectives on Massachusetts PMP (MassPAT)
2. Formative research to inform hypotheses in further quantitative, qualitative studies
Methods

- N=23
- Semi-structured interview guide (30-60min)
- Role play-based trainings
- Digital recording
- Transcription/Translation with quality checks
- Collaborative generation of coding scheme, based on emerging themes
- Double coding w/reconciliation

<table>
<thead>
<tr>
<th>Respondent Type</th>
<th>n</th>
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<tbody>
<tr>
<td>Prescriber</td>
<td>6</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>5</td>
</tr>
<tr>
<td>Law Enforcement/Regulator</td>
<td>7</td>
</tr>
<tr>
<td>User/Community Representative</td>
<td>5</td>
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Qualitative Component

- Interview Domains
  - Role and organization
  - Opioid crisis: origins, evolution, solutions
  - PMP: origins, evolution
  - PMP: typical, atypical use
  - PMP: Perception of impact (positive, negative)
  - Geonarratives: use of PMP-based maps
Major Findings

1. Participants’ perspectives on the origin and purpose of PDMP were closely split based on their professional affiliation.

2. Participants expressed frustration about lack of training and guidance on how to effectively read and utilize PDMP data—a problem not fixed by recent reforms.

3. Possible law enforcement access to and use of PDMP is a source of confusion, fear, and perceived potential detriment in addressing the opioid crisis.

4. PDMP’s potential benefit in curbing the opioid crisis is contingent on other risk reduction interventions.
Physicians currently believe that their prescribing practices are vulnerable to being monitored...I think it makes them withhold appropriate treatment and I think it destroys the physician-patient relationship between doctor or providers.

- Health Care Provider
No one taught me in medical school and there’s no notice from...the legislature that mandates it on how we’re supposed to use it... We need a lot more study and research to figure out what are the right ways and wrong ways to use it.

- Health Care Provider
A lot of people stay away from certain healthcare facilities or companies or whatever and because...of the way they’ve begun targeting us and treating us in terms of, as using the PMP as a tool of oppression.

- Drug User
Study 2: Social Listening Analysis

Goals:

1. Quantify prevalence of comments on PDMPs on Reddit
2. Conduct sentiment analysis of PDMP comments
3. Conduct content analysis of PDMP comments
Gather social media dataset from Reddit (can also use Facebook, Twitter, etc.)
Analyze for trends, sentiments, and emerging issues

Advantages

- User-initiated
- No study-related observer effect
- Real time
- User interaction
- Low cost
<table>
<thead>
<tr>
<th>Author Type</th>
<th>Sentiment Toward PDMPs</th>
</tr>
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<tbody>
<tr>
<td>1. Prescriber or dispenser</td>
<td>1. Positive</td>
</tr>
<tr>
<td>2. Patient or family member</td>
<td>2. Negative</td>
</tr>
<tr>
<td>3. Law enforcement or government regulator</td>
<td>3. Both positive and negative</td>
</tr>
<tr>
<td>4. None specified</td>
<td>4. None/point of information</td>
</tr>
</tbody>
</table>
Quantitative Results: Longitudinal

**Total PDMP-related Reddit Posts**

- **Total PDMP-related posts**

**Increase in PDMP posts as function of total Reddit posts**

- **Rate of PDMP posts within total posts**
Quantitative Results

Sentiment by Author Type

- Positive
- Negative
- Positive & Negative
- No Sentiment

- Total
- Patients & Family
- Prescribers & Dispensers
- Unidentified
It's great because it's black and white... I had a patient a few months ago asking for anti-anxiety meds (people using meth like it to 'come down', so it's big here).... Showed him the PMP, he smiles and goes "you got me" and walks out.

- User 321051JU
Secondary Analysis of Admin Data (2016-18)

- Collaboration with ACLU-MA, MIT Media Lab on privacy concerns within PDMPs and “auditing algorithms”
- FOIA request of Mass PDMP Data
- Preparation for possible litigation
Analysis of Administrative Data (‘16-18)

Average Yearly Searches of MassPAT vs Maven

- Maven (2011-2016): 591

Color Legend:
- Green: Law Enforcement
- Red: Fraud
- Orange: DPH Drug Control Program
Analysis of Administrative Data (‘16-18)

Total Number of MassPAT Searches from Law Enforcement

<table>
<thead>
<tr>
<th>MassPAT Roles</th>
<th>Number of Searches</th>
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<tbody>
<tr>
<td>DEA</td>
<td>1999</td>
</tr>
<tr>
<td>FBI</td>
<td>541</td>
</tr>
<tr>
<td>FDA</td>
<td>52</td>
</tr>
<tr>
<td>Local Police</td>
<td>1869</td>
</tr>
<tr>
<td>State Police</td>
<td>4269</td>
</tr>
<tr>
<td>Other Law Enforcement</td>
<td>2273</td>
</tr>
</tbody>
</table>
Analysis of Administrative Data (‘16-18)

Types of MassPAT Searches from Law Enforcement

- DEA: 1361 searches (553 Patient Searches, 808 Prescriber Searches, 2 Patient Searches, 0 Pharmacy Searches)
- FBI: 200 searches (100 Patient Searches, 100 Prescriber Searches, 0 Pharmacy Searches)
- FDA: 1 search (1 Prescriber Search)
- State Police: 3478 searches (0 Patient Searches, 3478 Prescriber Searches, 0 Pharmacy Searches)
- Local Police: 1733 searches (0 Patient Searches, 1733 Prescriber Searches, 0 Pharmacy Searches)
- Other Law Enforcement: 1971 searches (0 Patient Searches, 1971 Prescriber Searches, 0 Pharmacy Searches)
Legal Basis: Police Access

13 States Require Warrant for Out-of-State Law Enforcement Access

Evolving Jurisprudence: OR PDMP v DEA

Even assuming that the probable cause requirement is severable, the Oregon statute stands as an obstacle to the full implementation of the CSA because it "interferes with the methods by which the federal statute was designed to reach [its] goal." Gade, 505 U.S. at 103 (quoting Int’l Paper Co. v. Ouellette, 479 U.S. 481, 494 (1987)). By placing the initial burden of requiring a court order to enforce the subpoena upon the DEA, § 431A.865 interferes with the scheme Congress put in place for the federal investigation of drug crimes and thereby undermines Congress’s goal of "strengthen[ing] law enforcement tools against the traffic in illicit drugs." Gonzales, 545 U.S. at 10. Consequently, we hold that the two provisions are in “positive conflict”—Or. Rev. Stat. § 431A.865 is preempted by 21 U.S.C. § 876. We note, however, that this result preserves Oregon’s option to contest subpoenas for protected information and thus trigger the enforcement procedure described in § 876(c), a critical safeguard in light of the particularly important privacy interest implicated here.

REVERSED.
Physicians and patients have no reasonable expectation of privacy in the highly regulated prescription drug industry

- David Nutter, J
States Erected Law Enforcement Safeguards

13 States Require Warrant for Out-of-State Law Enforcement Access

States Erected Law Enforcement Safeguards

0* States Require Warrant for Out-of-State Law Enforcement Access

Health Systems Implications

1. Improve PDMP design, training to facilitate decision support function
2. Integrated PDMP data with EMRs
3. Assess and calibrate PDMP implementation
4. Extend privacy protections to PDMP data to raise provider, patient confidence
5. Change laws to protect from dragnet surveillance
Emerging Policy Trends

1. Several states (WI, ME, KY) now bundle PDMP and criminal justice data.
   - Not clear what “decision support” function these data are supposed to have

2. Ongoing litigation (*DOJ v. Jonas*)
Conflict or Synergy?

Privacy Protections = Essential to Public Health Surveillance

Privacy and Confidentiality

Community/Public Health Interests
Public Health Implications

- Chilling effect on addiction and pain therapy providers, resulting in defensive practice
- Deterrence to help-seeking for pain and drug treatment based on real or perceived risk
- Erosion of trust in providers, entire health care system for most vulnerable patients
- Missed opportunity to reduce harm
  1. Linkage to SUD treatment, other services
  2. Overdose education, naloxone prescription
  3. HIV prevention, other risk reduction assistance
1. Often, question isn’t what we should do, but why aren’t we doing it?
2. Translate research into policy: Massachusetts law changed to require a warrant for PDMP access
3. Addiction medicine stands to gain and to lose from tools like PDMPs, must actively engage in policy and design

Closing Thoughts
We knew that [transition to black market drugs] was going to be an issue, that we were going to push addicts in a direction that was going to be more deadly... But, we also know that you have to start somewhere.

Dr. Carrie DeLone
Pennsylvania’s Former Physician General
1. Study participants

2. Collaborators: Thomas Stopka, Sarah Seymour, Mina Hong, Lane M Bandanza, Erin Allison Crocker, Allison M Morgan

3. Tufts University CTSI 2016 Pilot Award Program, Stopka/Beletsky et al. (MPIs)
Questions?

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