Legal & Policy Approaches to Reducing Prescription Drug Overdose

August 28, 2014
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Overview

- Fatal opioid overdose is at epidemic levels
- Opioid overdose death is largely preventable
  - Evidence-based treatment is available
  - Overdose typically reversible w/ naloxone
- Law, regulation, policy and administrative inertia contribute to overdose in many ways
- When modifying law, policy and practice, the details are important
Reducing improper prescribing
- Use of PMPs with best practices
- Non-opioid therapy
- Prescriber and dispenser education
- Modification of insurance incentives (e.g. methadone as pain treatment)
- Care coordination
- Enforcement efforts

Addressing addiction
- Provider education
- Increased access to evidence-based treatment
- Acknowledgement of addiction as medical condition
- Pharmacy lock-in where appropriate
- Jail diversion programs

Improving access to overdose care
- Increased naloxone access and overdose response training for:
  - community members
  - first responders
- Good Samaritan 911 legislation
- Law enforcement education
Overview of the opioid pain reliever overdose epidemic

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August 28, 2014

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Dramatic increase in overdose deaths related to opioid pain relievers since 1999

CDC, National Center for Health Statistics, National Vital Statistics System
Opioid pain reliever-related overdose deaths increasing at a faster rate than deaths from any major cause.

% change in number of deaths, United States, 2000-2010

- Rx opioid overdose: 276%
- Alzheimer’s: 68%
- Hypertension: 47%
- Parkinson’s Disease: 40%
- Nephritis: 36%
- Suicide: 31%
- Liver Disease: 20%
- Chronic Lower Respiratory disease: 13%
- Septicemia: 11%
- HIV: 7%
- Malignant Neoplasms: 4%
- Pneumonitis: 2%
- Diabetes Mellitus: 0%
- Homicide: -3%
- Perinatal Period: -14%
- Heart disease: -16%
- Motor vehicle traffic: -22%
- Cerebro-vascular: -23%
- Influenza & Pneumonia: -23%
- Aortic Aneurysm: -34%

WISQARS, 2000 and 2010; CDC/NCHS, National Vital Statistics System
Middle-aged adults are at greatest risk for drug overdose in the United States

Death rates by age group

CDC/NCHS, National Vital Statistics System
Opioid pain reliever prescribing rates vary by state

Some states have more painkiller prescriptions per person than others.


CDC Vital Signs, July 2014. Rates per 100 people in 2012
Drug overdose death rate 2008 and opioid pain reliever sales rate 2010

Kg of opioid pain relievers used per 10,000
Age-adjusted rate per 100,000

National Vital Statistics System, DEA's Automation of Reports and Consolidated Orders System
States with more opioid pain reliever sales tend to have more drug overdose deaths.

Prescriptions filled and opioid pain reliever overdose deaths — New York City, 2008-2009

Rates of hydrocodone and/or oxycodone filled by NYC neighborhood

Rates of unintentional opioid pain reliever overdose deaths by NYC neighborhood

Opioid-related overdose death rates and treatment admissions increased over time along with opioid sales.

Half of US opioids market is treatment for chronic, non-cancer pain

U.S. opioids market revenues for 7 leading indications, 2010

Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths

Hazard ratio for opioid overdose death

1 - < 20 (reference)  | 20 - <50  | 50 - <100  | >= 100
---|---|---|---
chronic pain | 1.88 | 4.63 | 7.18
acute pain  | 1.58 | 4.73 | 6.64

Maximum prescribed daily dose, morphine milligram equivalents
Patients receiving high doses of opioid pain relievers account for disproportionate share of overdoses

Opioid pain reliever overdose deaths: key points

• Increasing at a faster rate than deaths from any major cause in the United States

• Increasing dramatically along with increased prescribing of opioid pain relievers

• Patients receiving opioids at high doses and from multiple prescribers at highest risk
Prescription Monitoring Programs (PMPs)

Databases that collect patient-specific controlled substance prescription data

Data are generated by dispensers at point of dispensing

Data can be accessed by authorized users such as medical professionals, pharmacies, and law enforcement

May be helpful in reducing over-prescribing, coordinating care, and improving public health surveillance
States with PMP Enabling Legislation
1998 - 2014

Total Number of States (and DC)

- Existing PMP legislation
- New PMP legislation
1 The operation of Nebraska’s Prescription Monitoring Program is currently being facilitated through the state’s Health Information Initiative. Participation by patients, physicians, and other health care providers is voluntary.

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PMP Best Practices: The Big 5
Monitor all federally controlled drugs as well as other drugs of abuse

Best Practice #1
Prescription Drug Monitoring Programs
States With Authority to Monitor Schedule II, III and IV Substances

1 Iowa’s PDMP monitors Schedule III and IV substances that the advisory council and the Board of Pharmacy determine can be addictive or fatal if not taken under the proper care or direction of a prescribing practitioner.

2 The Mayor of D.C. has approved the legislation enacting a PMP, but it is pending a 30-day review by Congress.

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Prescription Drug Monitoring Programs
States With Authority to Monitor Schedule V Substances

1Tennessee’s law authorizes the monitoring of Schedule V substances which have been identified by the controlled substances database advisory committee as demonstrating a potential for abuse.

This information was compiled using legal databases, state agency websites and direct communications with state PDMP representatives.
Please note that although a state may have statutory authority to monitor Non-controlled/Non-Scheduled substances, that state may not currently be monitoring prescriptions for such substances and may in fact require implementation of additional regulations before that monitoring can commence.

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Best Practice #2

Proactively provide data to authorized users
Unsolicited PMP Reports/Info to Prescribers, Pharmacists, Law Enforcement and Licensing Entities

1 North Carolina provides unsolicited reports to the Attorney General who has the discretion to forward the information to law enforcement. 2 Michigan send alerts to physicians when a patient surpasses the threshold but does not send the actual report. 3 The Maryland provision goes into effect on October 1, 2014.

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Best Practice #3

Ensure that data is timely & easily accessible
1 New York requires the submission of data in real time by statute, but that has been interpreted by regulation to mean no later than 24 hours after the substance is delivered.  
2 Ohio requires submission of data from pharmacies daily and from wholesalers monthly.  
3 Utah requires submission weekly, but for those participating in the statewide pilot program, submission is required daily.  
4 Michigan requires daily reporting for online reporting of dispensing information and weekly for mail-in submission of data.  
5 Indiana will begin requiring the submission of data within 3 days by July 1, 2015 and within 24 hours by January 1, 2016.  
6 Louisiana begins daily reporting on August 1, 2014.  
7 Tennessee will begin requiring daily submission on January 1, 2016.  
8 Connecticut requires marijuana dispensaries to report marijuana dispensing to the PMP daily.

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1 Oregon will only allow direct access to the PMP to practitioners in CA, ID, and WA.  

2 Oklahoma will begin sharing data with other PMPs on November 1, 2014.
Best Practice #4

Ensure that all authorized users are trained on PMP goals and usage.
States that Require Authorized Users to Undergo Training for Use of PMP

Authorized users with direct access to the PMP

Law enforcement officials only

Employees of the Cabinet for Health and Family Services only

1 Law enforcement officials in Vermont do not have access to the PMP, but must undergo training before being allowed access to PMP data provided to them by licensing boards.

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Use de-identified data to reveal trends & evaluate PMP
Types of Authorized Recipients - De-identified Data

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Mandatory registration & (at least in some cases) use
Dedicated funding mechanisms
Linkage to addiction treatment professionals
Easy linkage to other health data
States that Require Prescribers and/or Dispensers to Access PMP Information in Certain Circumstances*

* Please see the accompanying memorandum for specifics as to the circumstances under which a prescriber and/or dispenser is obligated to access the PMP database in each state.

1 The Virginia provision goes into effect on July 1, 2015. 2 A number of the Ohio provisions go into effect on April 1, 2015.

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Emerging evidence that PMPS can:

- Inform sound clinical prescribing decisions
- Reduce “doctor shopping”
- Assist medical examiner practice
- Provide non-patient-specific surveillance
Increased Naloxone Access
Naloxone overview

- Prescription medication
- Not a controlled substance
- No abuse potential
- Extremely good risk profile
- Reverses clinical and toxic effects of opioid overdose
Barriers to Naloxone Access

Prescriber liability concerns

Many high-risk individuals do not request and are not offered naloxone

Bystanders often fail to summon first responders

Many first responders do not carry naloxone
Naloxone Access/Good Samaritan Best Practices: The Big 4
Best Practice #1

Limit liability for naloxone prescribers & administrators acting in good faith
Best Practice #2

Non-patient specific prescription
Best Practice #3

Provide criminal immunity to Good Samaritans comprehensive enough to change behavior
Best Practice #4

Modify scope of practice so that properly trained first responders can administer naloxone.
Feasibility

Piper et al. Subst Use Misuse 2008: 43; 858-70
Walley et al. JSAT 2013; 44:241-7 (Methadone and detox programs)

Increased knowledge & skills

Green et al. Addiction 2008: 103;979-89

No increase in use, increase in drug treatment


Reduction in community overdose

Maxwell et al. J Addict Dis 2006:25; 89-96
Walley et al. BMJ 2013; 346: f174

Cost-effectiveness

Support for Increased Naloxone Access

American Medical Association
American Pharmaceutical Association
American Public Health Association
American Society of Addiction Medicine
Attorney General of the United States
National Association of Drug Diversion Investigators
Office of National Drug Control Policy
U.S. Conference of Mayors
States with naloxone access and drug overdose Good Samaritan laws

States with drug overdose Good Samaritan laws only

States with naloxone access laws only

States with naloxone access and drug overdose Good Samaritan laws only
States with Naloxone Access Laws, 2001 - 2014

States With Naloxone Access Laws, 2001-2014

Total Number of States (and DC)


Newly-passed laws
Existing laws
States with Good Samaritan laws, 2007 - 2014

States With Good Samaritan Laws, 2007-2014

Total Number of States (and DC)

Newly-passed laws
Existing laws
Parting Thoughts

• Many other laws affect overdose risk

• Changing law is not magic bullet
  – Changing practice requires engagement with and action from public health and elected officials, the medical and treatment communities, law enforcement, clergy, community groups, etc.

• Must address overdose throughout the continuum

• As with all policy interventions, results should be independently and rigorously evaluated
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Additional Resources

The Network for Public Health Law
www.networkforphl.org

The National Alliance for Model State Drug Laws
www.namsdl.org

CDC National Center for Injury Prevention and Control
www.cdc.gov/Injury

CDC Public Health Law Program
www.cdc.gov/phlp

PDMP Center of Excellence, Brandeis University
www.pdmpexcellence.org

LawAtlas
www.lawatlas.org
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