Balancing Access and Use of Opioid Therapy

Challenges Confronting Health Plans, Payers, Prescribers and Others

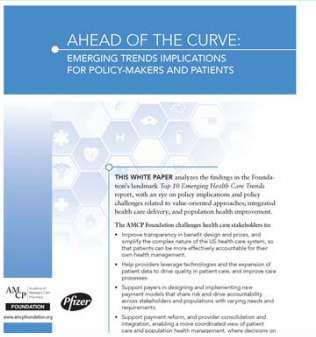
AMCP Academy of Managed Care Pharmacy

FOUNDATION

6th ANNUAL RESEARCH SYMPOSIUM

Welcome

Paula J. Eichenbrenner, CAE
AMCP Foundation Executive Director



AMCP Academy of Managed Care Pharmacy FOUNDATION | Balancing Access and Use of Opioid Therapy | 6th Annual Research Symposium

Welcome

Brett Norman
Symposium Moderator
POLITICO Health Policy Editor

AMCP Foundation | Balancing Access and Use of Opioid Therapy | 6th Annual Research Symposium

Overview on Opioid Pain Therapy Misuse and Abuse and Federal Initiatives

Christopher M. Jones, PharmD, MPH
Director, Division of Science Policy
Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services (HHS)

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The Opioid Epidemic and the Federal Response

Christopher M. Jones, PharmD, MPH
CDR, US Public Health Service
Director, Division of Science Policy
Office of the Assistant Secretary for Planning and Evaluation

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Assistant Secretary for Planning and Evaluation

Overview

- Epidemiological trends
- HHS Opioid Initiative
- Conclusions

EPIDEMIOLOGICAL TRENDS

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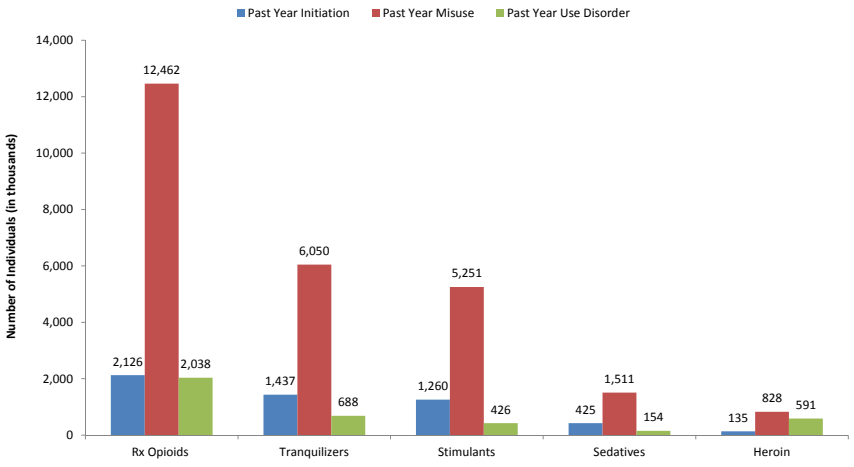
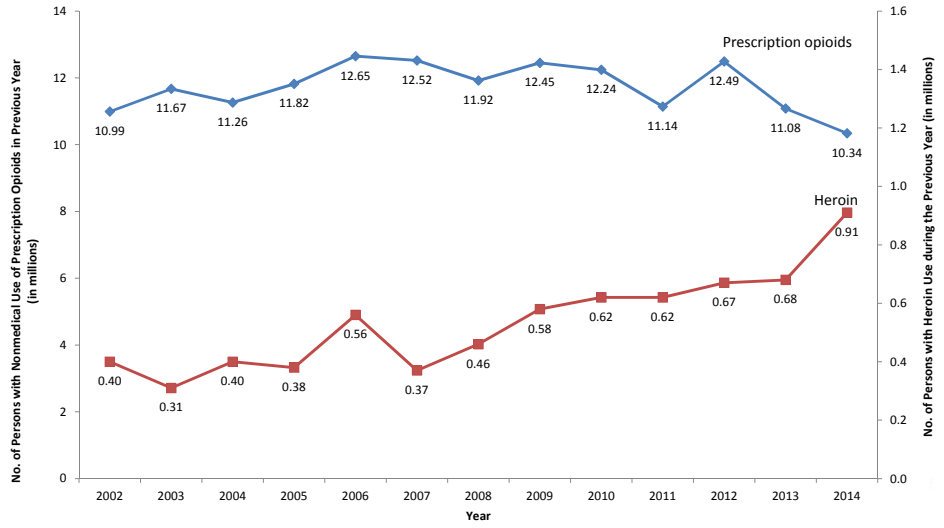
Office of the Assistant Secretary for Planning and Evaluation

Prescription Drug Misuse and Heroin Use, 2015

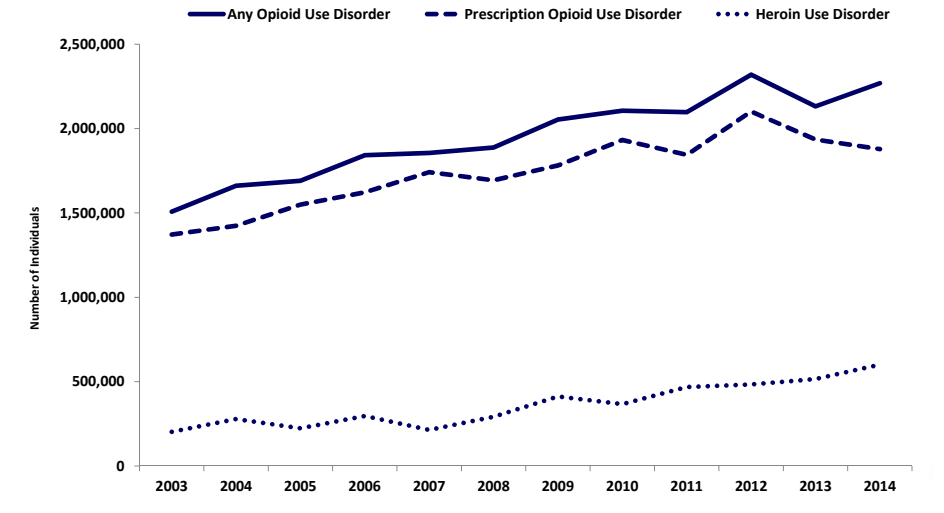


Past year nonmedical use of prescription opioids and heroin use



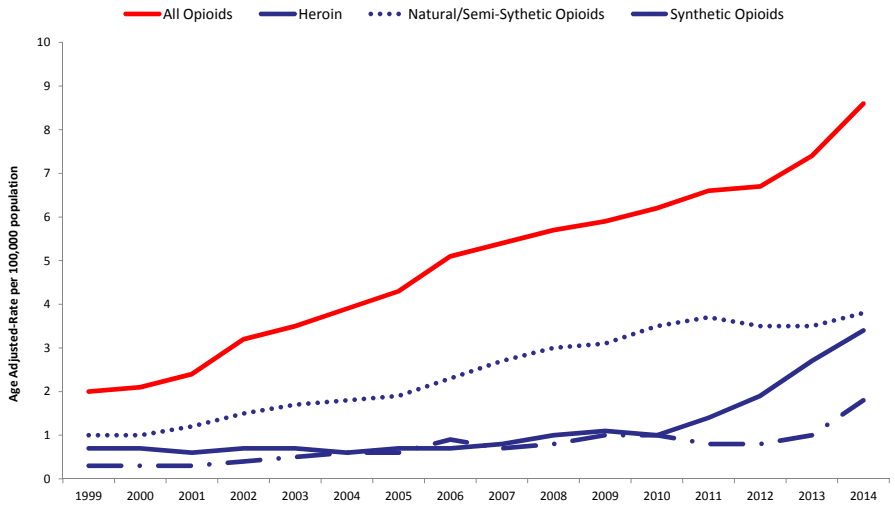
Source: SAMHSA, NSDUH 2002-2014 PUF

Past year opioid use disorders, US, 2003-2014



Source: SAMHSA, NSDUH 2003-2014 PUF

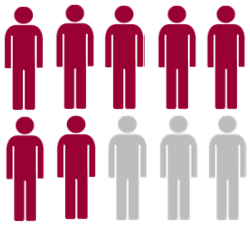
Opioid-related overdose deaths, US, 1999-2014



Source: CDC, NVSS, 2016

Nonmedical use of Rx opioids significant risk factor for heroin use

3 out of 4 people
who used heroin in the past year misused opioids first

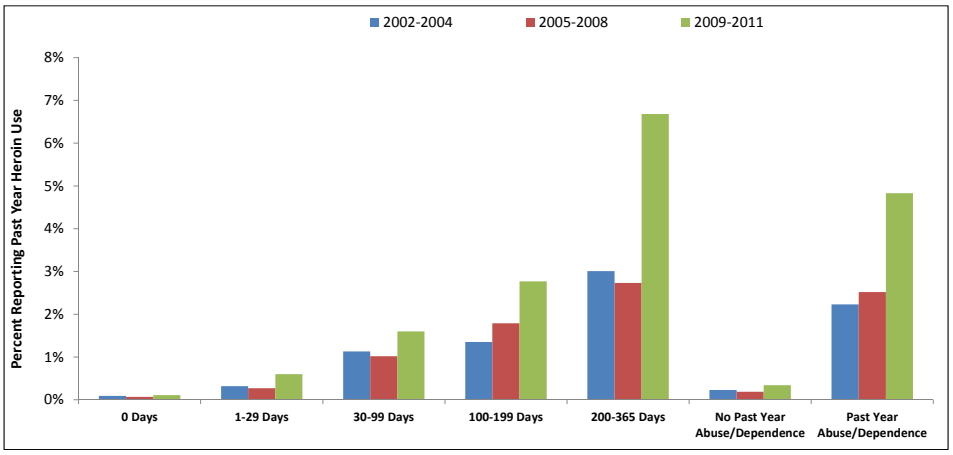


7 out of 10 people
who used heroin in the past year also misused opioids in the past year

Source: Jones, C.M., Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002–2004 and 2008–2010. Drug Alcohol Depend. (2013). Slide credit – Grant Baldwin, CDC

Frequent nonmedical users of Rx opioids and those with abuse/dependence most likely to initiate heroin

- 3.6% of nonmedical users of Rx opioids had initiated heroin use within 5 years of initiating nonmedical use
- Initiation rate of <1.0% per year

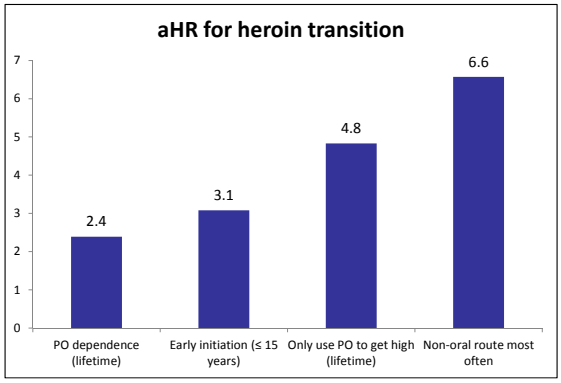


Source: Muhuri et al. , Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. SAMHSA, 2013

Heroin initiation rates among people nonmedically using Rx opioids

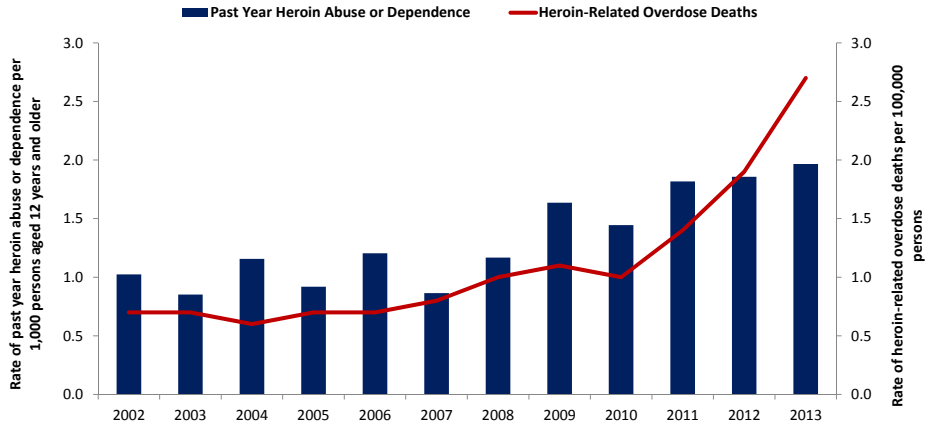
- Carlson et al – 2016
- Columbus, Ohio
- Age 18-23 at recruitment in 2009-2010
- NMU of Rx opioids ≥ 5 day in past 90 days
- No Hx of lifetime opioid dependence
- No Hx of heroin use or IDU
- Not involved in CJ system or SUD Tx in past 30 days
- Followed for 3 years

- 27 of 362 (7.5%) initiated heroin use during 36 months of study
- Transition rate of 2.8% per year



Source: Carlson et al. Drug Alcohol Depend. 2016;160:127-134

Rise in heroin overdose deaths strongly correlated with increase in heroin abuse or dependence



Source: Jones CM, Logan J, Gladden M, Bohm M, Demographic and substance use trends among heroin users, US, 2002-2013. MMWR, 2015.

Circumstances of Rx opioid nonmedical use and heroin initiation

Harocops et al., 2016

- Interviews between 8/2013 and 1/2015
- Cycle of oral to intranasal to injection
- Dependence, social context, economics, and availability all factors in heroin initiation
- Median time from first Rx opioid misuse to heroin use was 3 years
- Among those with no Hx of IDU prior to heroin initiation, median time between intranasal and IV heroin use was 6 months

Source: Harocops et al., Int J Drug Policy 2016;28:106-112

Multiple facets of the opioid epidemic

Morbidity and Mortality Weekly Report

Community Outbreak of HIV Infection Linked to Injection Drug Use of Oxymorphone — Indiana, 2015

Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009 to 2012

SW Patrick, MM Davis, CU Lehman and WO Cooper

Journal of Perinatology (2015) **35,** 667. doi:10.1038/jp.2015.63

Morbidity and Mortality Weekly Report

May 8, 2015

Increases in Hepatitis C Virus Infection Related to Injection Drug Use Among Persons Aged ≤30 Years — Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012

PUBLIC HEALTH

Heroin, Opioid Abuse Put Extra Strain On U.S. Foster Care System

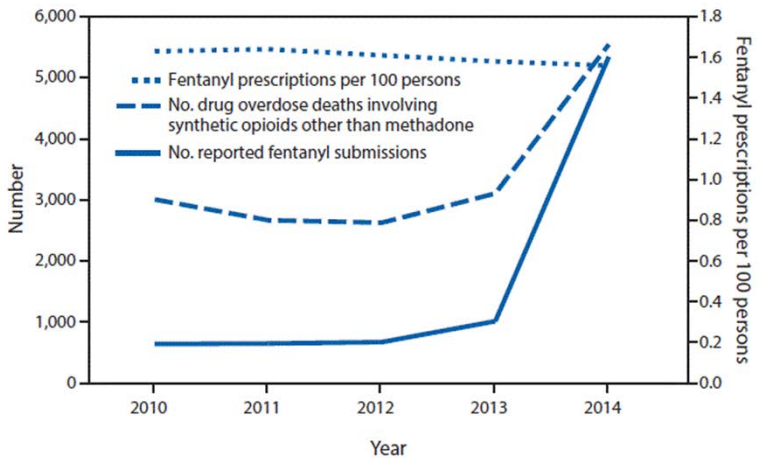
October 27, 2015 · 4:28 PM ET

Heard on All Things Considered

CBS NEWS | *August 25, 2016, 6:54 PM*

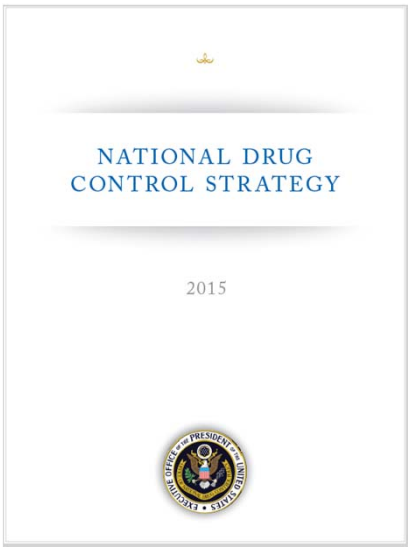
Dozens of Ohio overdoses blamed on heroin mixed with elephant tranquilizer

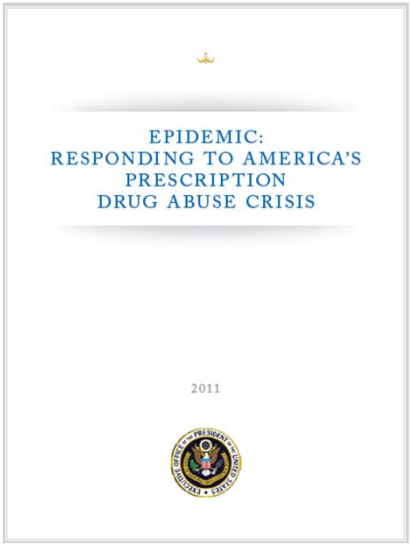
Synthetic opioid deaths closely linked to fentanyl submissions



Source: Gladden RM, et al. MMWR August 2016.

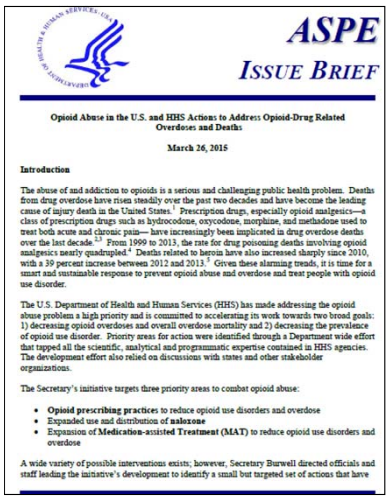
Administration's Approach





HHS Opioid Initiative

- Launched by Secretary Burwell in March 2015
- Three focus areas
  - Improve opioid prescribing
  - Increase use of naloxone to reverse opioid overdose
  - Expand use of Medication-Assisted Treatment (MAT) for opioid use disorders



ASPE
ISSUE BRIEF

Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths

March 26, 2015

Introduction

The abuse of and addiction to opioids is a serious and challenging public health problem. Deaths from drug overdose have risen steadily over the past two decades and have become the leading cause of injury death in the United States.[1] Prescription drugs, especially opioid analgesics—a class of prescription drugs such as hydrocodone, oxycodone, morphine, and methadone used to treat both acute and chronic pain— have increasingly been implicated in drug overdose deaths over the last decade.[2,3] From 1999 to 2013, the rate for drug poisoning deaths involving opioid analgesics nearly quadrupled.[4] Deaths related to heroin have also increased sharply since 2010, with a 39 percent increase between 2012 and 2013.[5] Given these alarming trends, it is time for a smart and sustainable response to prevent opioid abuse and overdose and treat people with opioid use disorder.

The U.S. Department of Health and Human Services (HHS) has made addressing the opioid abuse problem a high priority and is committed to accelerating its work towards two broad goals: 1) decreasing opioid overdoses and overall overdose mortality and 2) decreasing the prevalence of opioid use disorder. Priority areas for action were identified through a Department wide effort that tapped all the scientific, analytical and programmatic expertise contained in HHS agencies. The development effort also relied on discussions with states and other stakeholder organizations.

The Secretary's initiative targets three priority areas to combat opioid abuse:

- **Opioid prescribing practices** to reduce opioid use disorders and overdose
- Expanded use and distribution of **naloxone**
- Expansion of **Medication-assisted Treatment (MAT)** to reduce opioid use disorders and overdose

A wide variety of possible interventions exists; however, Secretary Burwell directed officials and staff leading the initiative's development to identify a small but targeted set of actions that have

IMPROVING OPIOID PRESCRIBING

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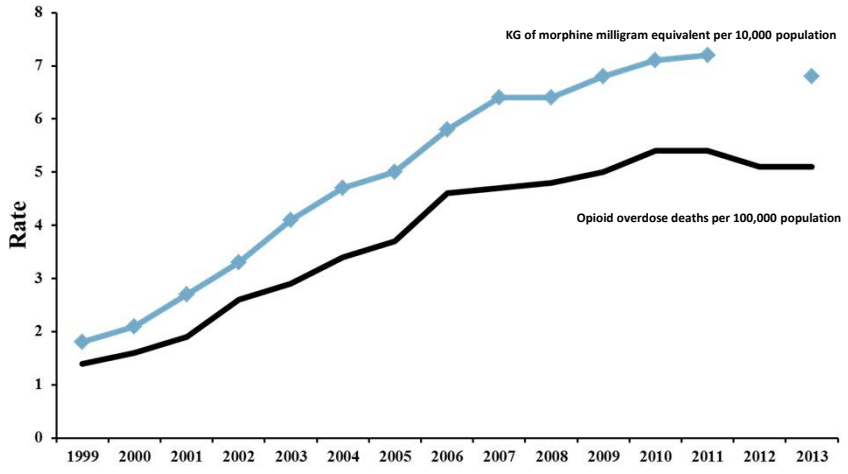
Increases in Rx opioid prescribing coincide with increases in Rx opioid overdose deaths



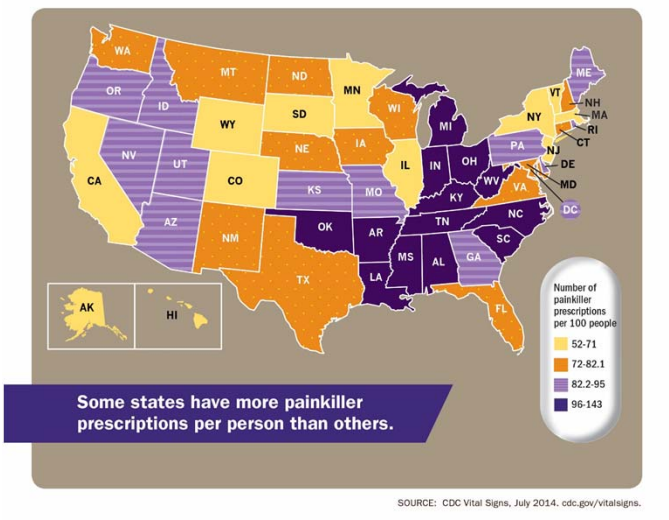
Source: Analysis of CDC National Vital Statistics Data and DEA ARCOS data,1999-2013.

Changes in prescribing trends

- High dose prescribing
- Longer duration
- Prescribing for conditions that don't really benefit from opioids
- Multiple providers/multiple pharmacies
- Opioid and benzodiazepine combination
- Opioids and alcohol and other sedating drugs

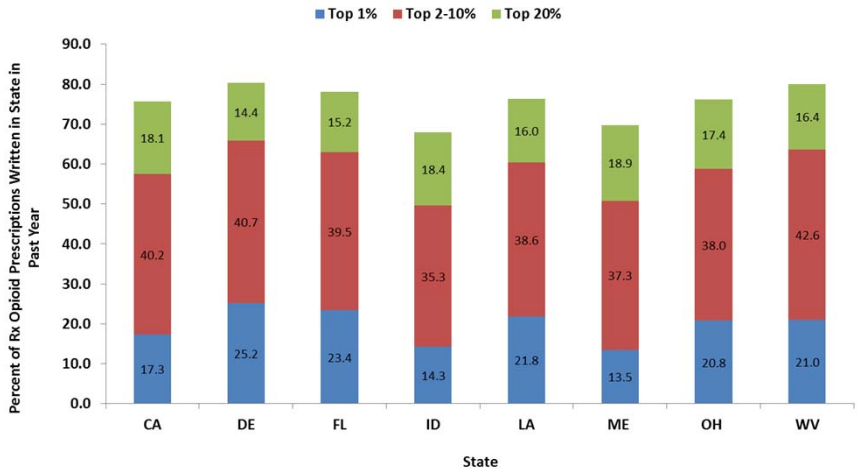
Source: Hwang et al., 2016. AJPM

Rx opioid prescribing rates vary by state



Source: CDC Vital Signs, July 2014. Rates per 100 people in 2012

Small percent of providers prescribe majority of Rx opioids



Source: Unpublished PBSS Data 2015

Improve opioid prescribing

- CDC opioid prescribing guidelines
- CDC Prevention for States funding
- Educational programs from FDA, NIDA, SAMHSA
- EHR/Clinical decision support
- Recent PR on HCAHPS
- IHS PDMP policy
- Implementation of the National Pain Strategy
- Engagement with health profession community

EXPANDING ACCESS TO MAT

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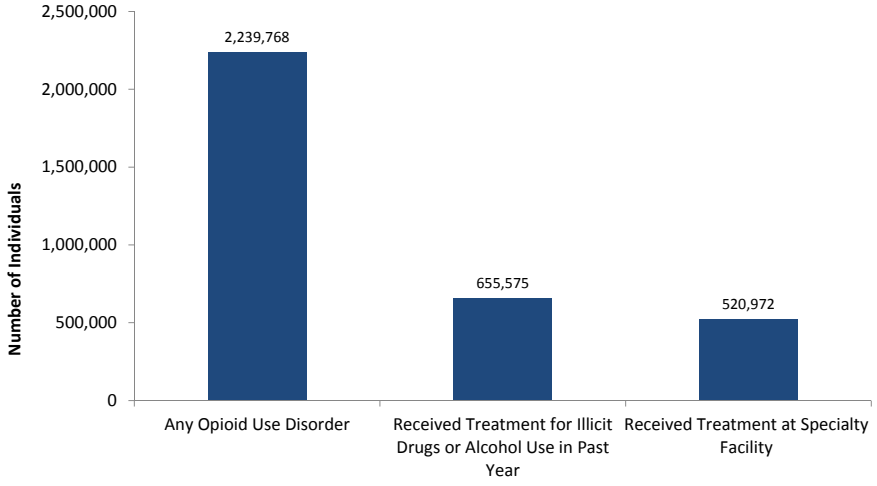
Office of the Assistant Secretary for Planning and Evaluation

People with opioid use disorders are not receiving treatment



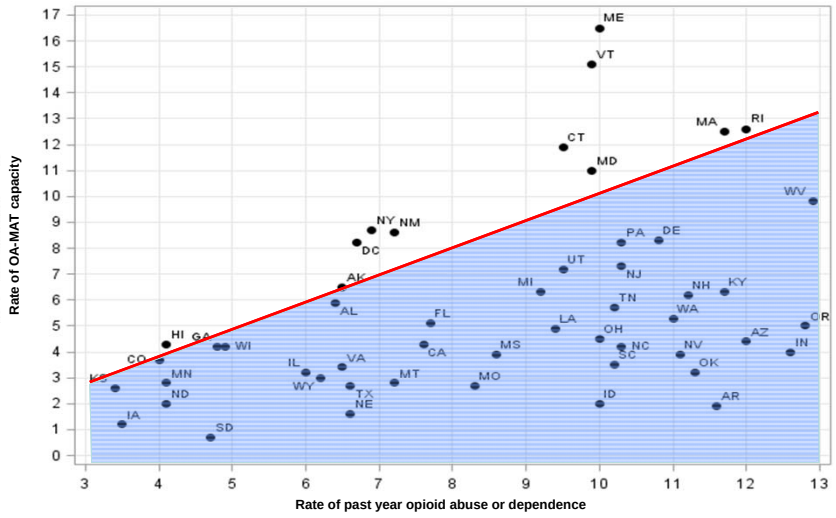
Source: Jones CM 2016 NSDUH PUF

Reasons why people didn't get treatment

Reason	Percentage
Treatment Cost/No Insurance/Insurance didn't cover treatment	47.8
Not ready to stop use/Didn't feel need for treatment/Could handle problem without treatment	35.0
Stigma	30.2
Awareness of treatment	12.3
Other	11.7
Availability of treatment	10.2

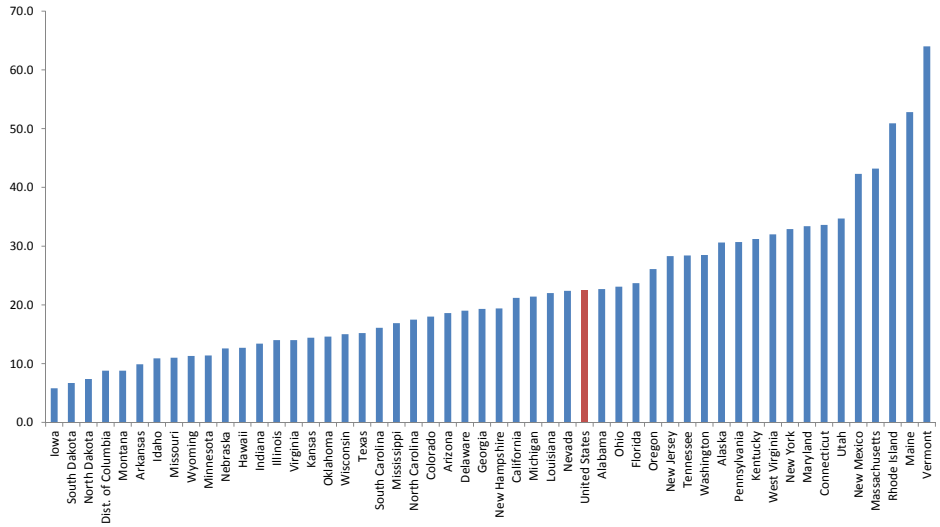
Source: Jones CM 2016 NSDUH PUF

Opioid abuse and dependence exceeds OA-MAT capacity in most states

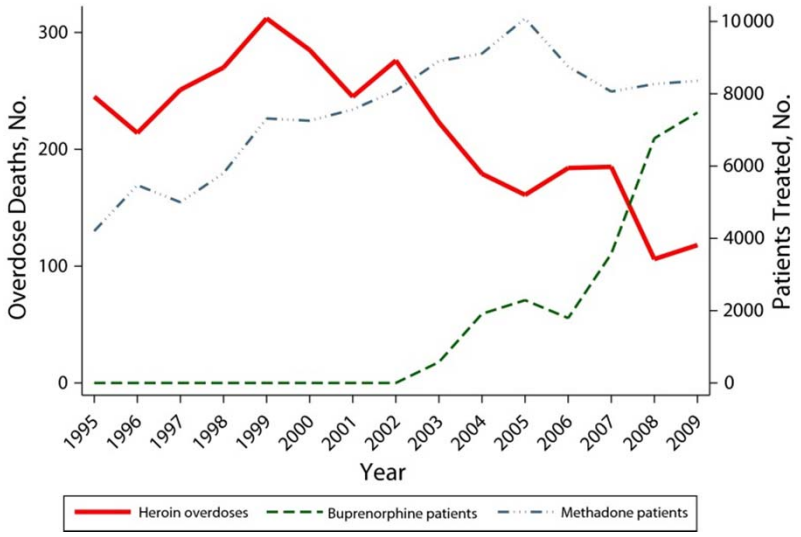


Source: Jones CM, Campopiano M, Baldwin G, McCance-Katz E. National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment. American Journal of Public Health, 2015;e1-e9.

Number of DATA waived physicians per 1,000 Active Physicians, 2014



Heroin overdose deaths and opioid agonist treatment: Baltimore, MD, 1995–2009.



Schwartz RP, Gryczynski J, O'Grady KE, Sharfstein JM, Warren G, Olsen Y, Mitchell SG, Jaffe JH. Opioid agonist treatments and heroin overdose deaths in Baltimore, Maryland, 1995-2009. Am J Public Health. 2013;103(5):917-22.

HHS efforts to expand access to MAT

- Approval of Probuphine
- Buprenorphine patient limit final rule
- SAMHSA grants to states in FY15 and FY16
- HRSA $94 million for MAT in Community Health Centers
- AHRQ grants for MAT in rural primary care
- Parity
- Medicaid expansion
- CARA

FY 17 Budget Request

INCREASING USE OF NALOXONE

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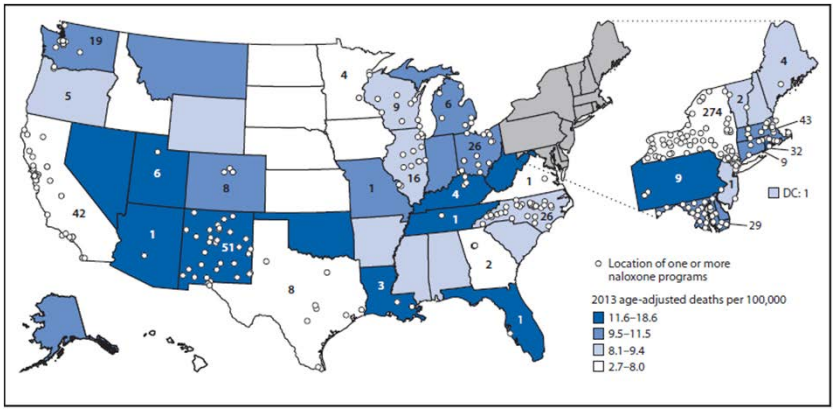
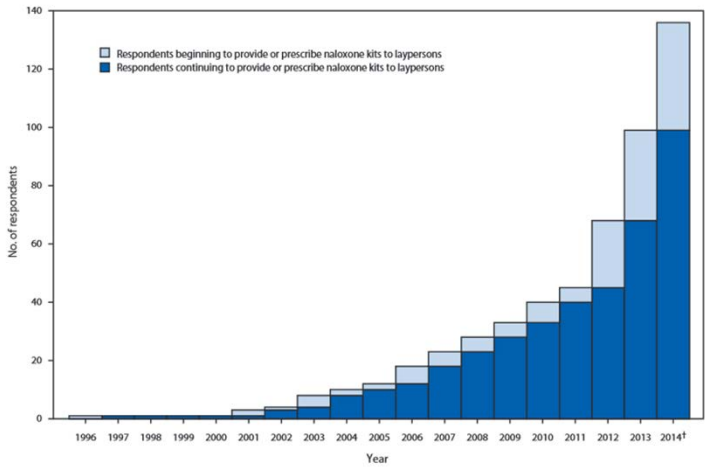
Number* and location of local drug overdose prevention programs providing naloxone to laypersons and age-adjusted drug overdose death rates



Source: Wheeler E, Jones TS, Gilbert MK, Davidson PJ. MMWR 2015

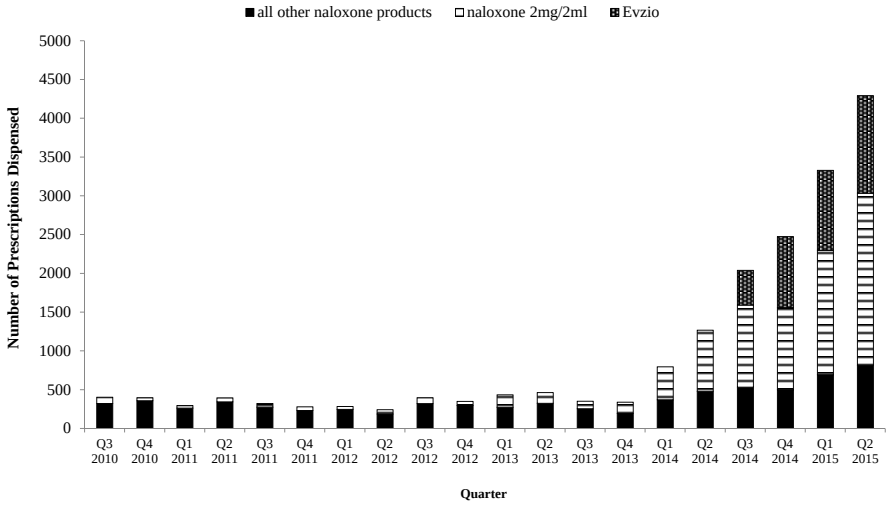
Rapid increase in naloxone distribution in the US, 1996-2014

FIGURE 1. Number of survey respondents reporting beginning or continuing to provide naloxone kits to laypersons, by year — United States, 1996–June 2014*†



Source: Wheeler E, Jones TS, Gilbert MK, Davidson PJ. MMWR 2015

Pharmacy dispensing of naloxone in the US, 2010-2015



Jones CM et al. 2016. Increase in naloxone prescriptions dispensed in US retail pharmacies since 2013. AJPH 106:689-90

Increase use of naloxone

- FDA and NIDA support to develop new formulations
- SAMHSA overdose toolkit
- Funding for states and communities to purchase, train, and distribute naloxone
  - HRSA funding to 18 rural communities in 2015
  - $11 million for SAMHSA state grants in FY16
- Support state-level efforts to expand access

Conclusions

- There is a continued urgency to address the public health crisis of opioid misuse, use disorder, and overdose
- Improving prescribing is a critical component
- Early identification of problematic opioid use and engagement in appropriate levels of treatment are critical in preventing morbidity and mortality
- Expansion of naloxone is needed
- Collaboration with all key stakeholders is paramount

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AMCP Foundation 6th Annual Research Symposium

Managed Care Pharmacy's Leadership & Opportunities in CARA Implementation

Susan A. Cantrell, RPh, CAE
AMCP CEO
AMCP Foundation Chair

Scope of Opioid Addiction Problem

- Nearly 2 million Americans suffered substance use disorders related to opioids (2014). An additional 586,000 people were addicted to heroin.

  (Substance Abuse and Mental Health Services Administration).
- Overdose deaths from all opioids have increased by 200 percent since 2001.
- Opioids were involved in 61 percent of the more than 47,000 U.S. drug overdose deaths in 2014.

  (Centers for Disease Control)

Scope of Opioid Addiction Problem

- Payments for opioid dependency or abuse increased 1,375 percent — from roughly $32 million in 2011 to nearly $446 million in 2015.
- Insurers paid an average of $19,333 for patients with an opioid abuse or dependence diagnosis — 563 percent more than the $3,435 average paid for all patients.
- From 2007 to 2014, insurers saw 3,200 percent increase in claims containing an opioid dependence diagnosis.

(FAIR Health, Inc.)

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2014 Partnership Forum

Partnership Forum: 'Breaking the Link Between Pain Management and Opioid Use Disorder'

- Holistic and evidence-based approach to pain management and OUD treatment
- Engage patient in decision-making process
- Include coordination with medical, pharmacy, behavioral and mental health care givers
- Seamlessly supported by a technology infrastructure.

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2014 Partnership Forum

- Conduct continuing pharmacy education programs
- Develop a best practices toolkit on pain management
- Actively promote quality standards for OUD prevention and treatment

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2014 Partnership Forum

Collaborate with organizations representing addiction treatment experts and managed care to review current practices and identify areas for substantial improvements in patient outcomes.

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Addiction Treatment Advisory Group (ATAG)

Diverse stakeholders:

Behavioral health organizations, outpatient treatment centers, nonprofit advocacy groups, health plans, pharmacy benefit management companies, specialty pharmacies, employers, hospitals and manufacturers.

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Addiction Treatment Advisory Group (ATAG)

ATAG's objectives:

- Identify and prioritize areas with the greatest potential to significantly improve patient outcomes;
- Develop recommendations to remove barriers, improve processes and modify systems to improve outcomes;
- Serve as advocates in adopting recommended changes;
- Support development of educational programs for managed care decision makers.

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ATAG Recommendations

Evaluate and update, as needed, managed care policies, processes, and benefit designs related to substance use disorders based on current evidence and evolving understanding of substance use disorders as chronic health conditions.

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ATAG Recommendations

Enhance continuity of care for patients with substance use disorders by actively managing transitions of care between sites of care, and between medical, pharmacy and mental health needs.

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ATAG Recommendations

Improve health care professional and patient awareness of, and access to, medications used in the treatment of substance use disorders.

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Comprehensive Addiction and Recovery Act

CARA creates a framework for opioid abuse prevention and treatment:

- Authorizes $181 million in new spending to strengthen efforts at prevention, treatment and recovery

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CARA: Roles for Pharmacists

- Member of Task Force on Pain Management.
- Grants to pharmacists for strategies to dispense medications for emergency treatment of suspected overdoses.
- Drug management programs ("lock-in" programs).
- Pharmacists will be part of HHS stakeholders group to provide input on impact of drug management programs, and defining "at-risk" populations.

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CARA Reauthorizes NASPERS

National All Schedules Prescription Electronic Reporting Act

1. NASPERS provides grants to state prescription drug monitoring programs (PDMPs).
2. Grants encourage states to improve PDMPs by increasing interoperability and the use of health-IT, e-health records, health information exchanges and e-prescribing.

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AMCP Advocacy on CARA

Task Force on Pain Management

Improve Access to Overdose Treatment

NASPER Reauthorization

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AMCP Advocacy on CARA

Task Force on Pain Management

Improve Access to Overdose Treatment

NASPER Reauthorization

Medication-assisted Treatment for Recovery

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Conclusion

Managed care plays a central role in such things as:

Population management
Appropriate medication selection
Care coordination
Provider education

Uniquely positioned to provide solutions to this problem.

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The Path of Pain: Maze or Labyrinth?

Glenna M. Crooks, Ph.D.
Founder and CEO

Strategic Health Policy International, Inc.
and
SageLife, LLC

Glenna@glennacrooks.com
Glenna@sagemylife.com
215-545-2023

Know the difference?

Maze

Labyrinth

Garden Labyrinth

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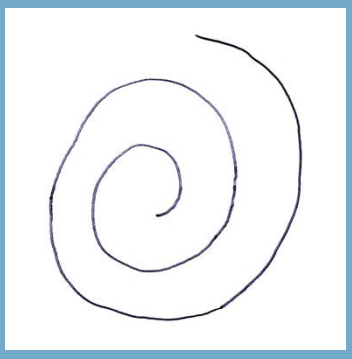
My Path of Pain



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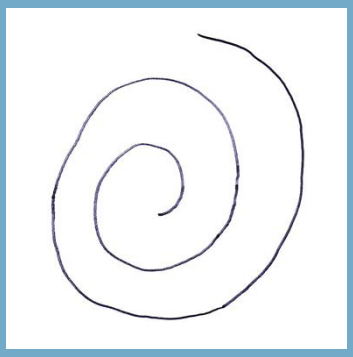
The Labyrinth Metaphor



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Hidden Spiral Labyrinth

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Overview

- Personal patient experience
- Pain history
- Pain impact
- Pain-relief methods

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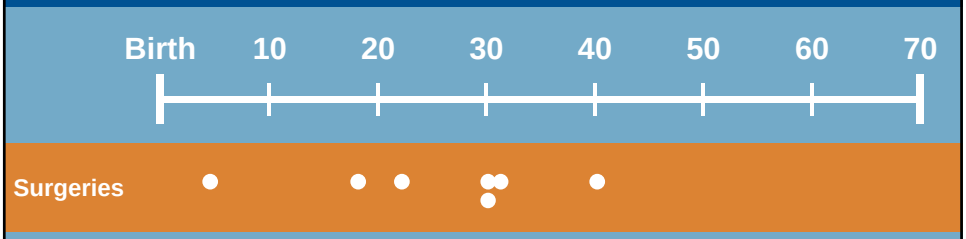
Surgeries Timeline



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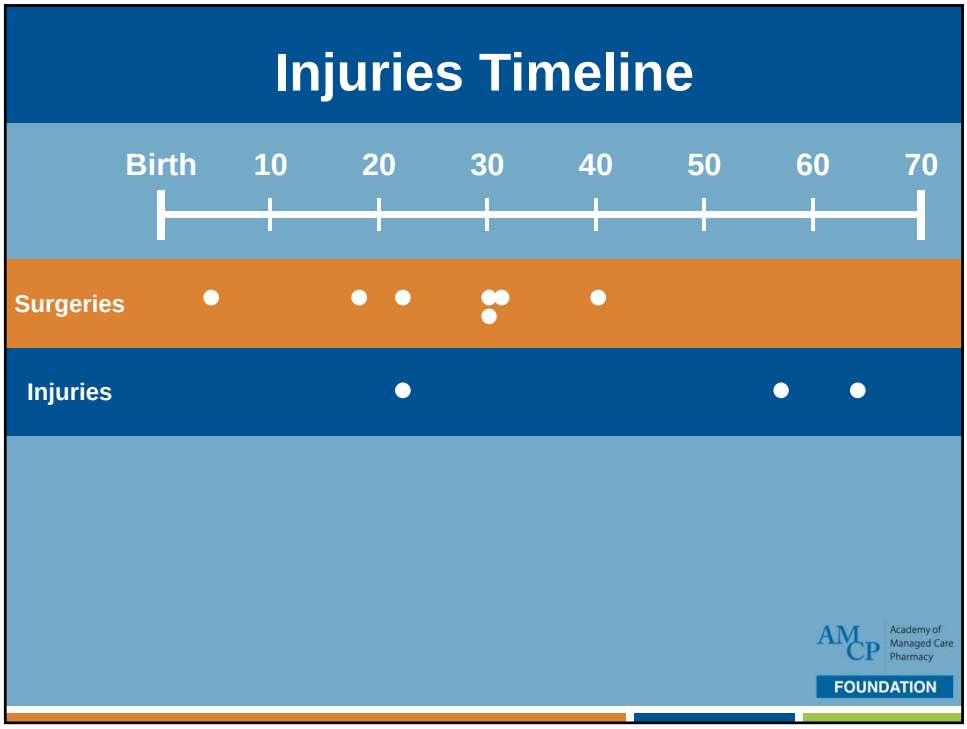
Injuries Timeline
Birth
10
20
30
40
50
60
70
Surgeries
Injuries
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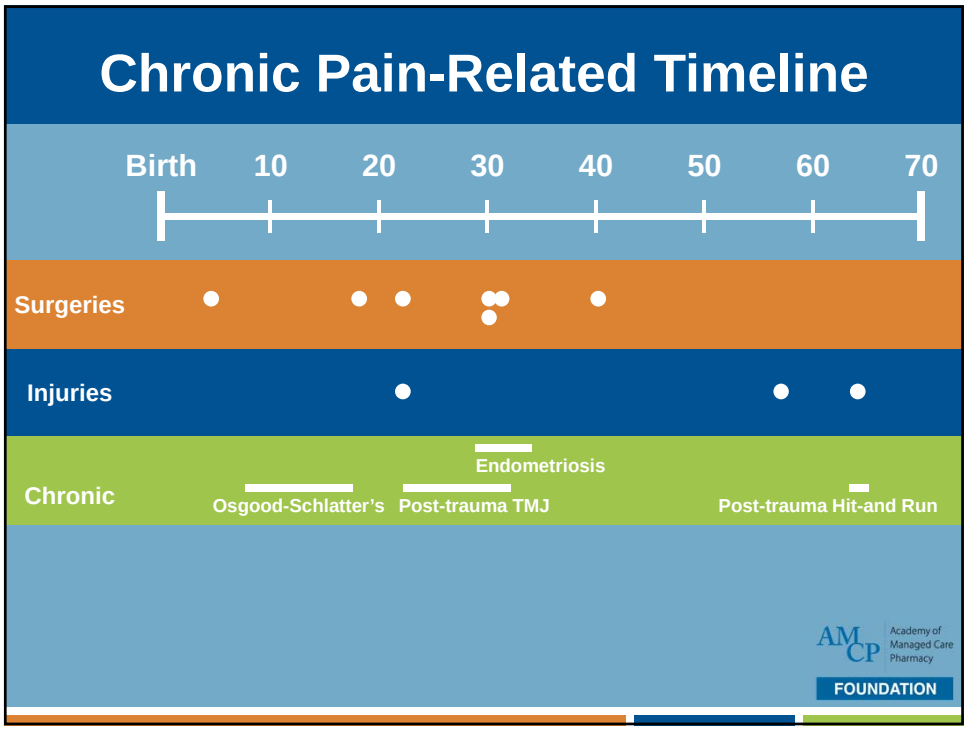
Chronic Pain-Related Timeline
Birth
10
20
30
40
50
60
70
Surgeries
Injuries
Chronic
Endometriosis
Osgood-Schlatter's
Post-trauma TMJ
Post-trauma Hit-and Run
AMCP
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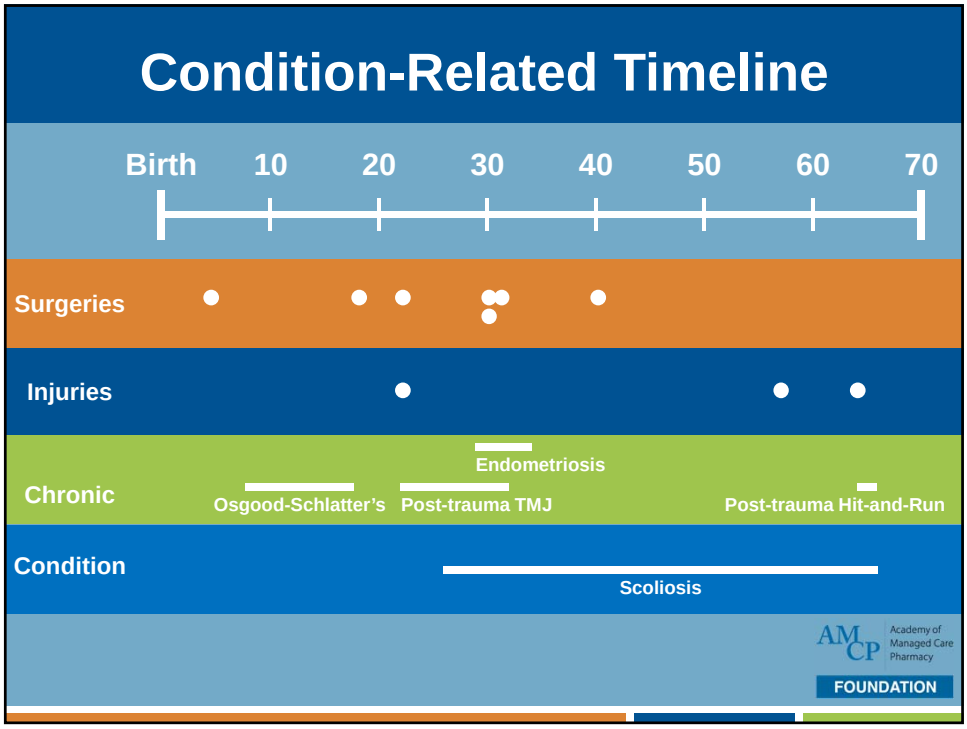
Condition-Related Timeline
Birth
10
20
30
40
50
60
70
Surgeries
Injuries
Chronic
Endometriosis
Osgood-Schlatter's
Post-trauma TMJ
Post-trauma Hit-and-Run
Condition
Scoliosis
AMCP
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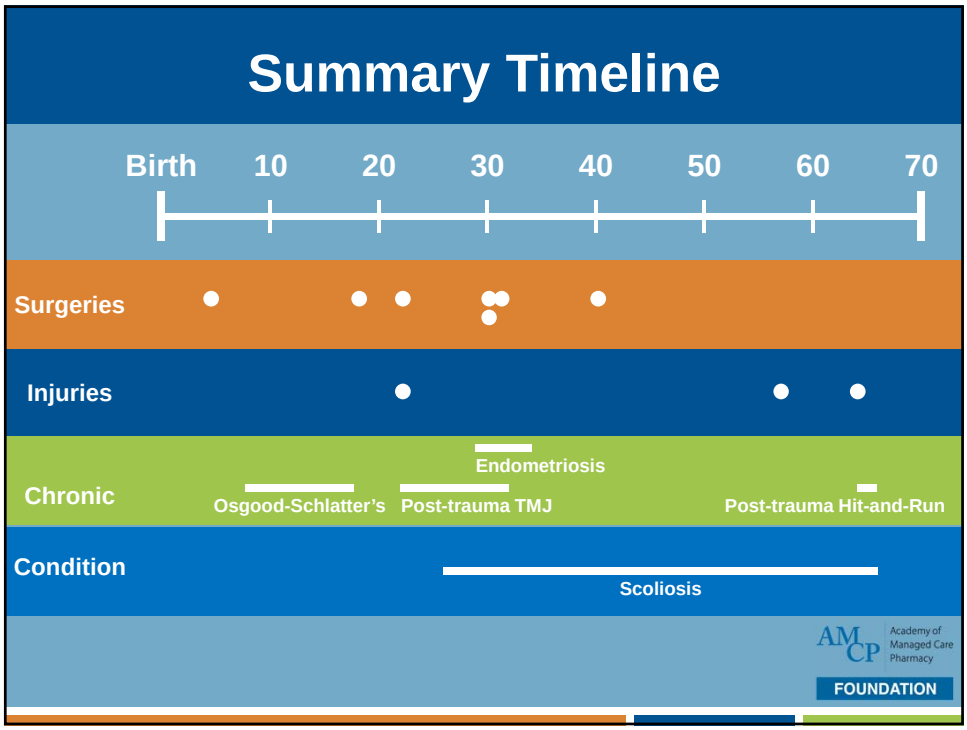
Summary Timeline
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Condition
Scoliosis
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"In Your Face" Impact

Grief, Loss, Longing

- Normalcy
- Wholeness
- Relaxation
- Safety
- Confidence in the body
- Trust in others
- Idealization of others
- Authenticity
- Life meaning

Other

- Fear
- Vulnerability
- Helplessness
- Shame
- Alienation from self/others
- Rejection/social isolation
- Anger-Depression Loop
- Constriction

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Early Pain Management

Professionals

- Physicians
- Surgeons
- Dentists

Products

- Tylenol with Codeine #3, 1-2 days post-op
- OTC Pain Relievers

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Later Pain Management

Professionals

- Physicians
- Clinical Researchers

Products

- Motrin + Valium, one dose in TMJ clinical trial
- OTC Pain Relievers
- Metaxalone
- Modafanil

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Canyon Ranch Alternative "Finds"

- Acupuncture
- Strength training
- Eye Movement Desensitization & Reprocessing
- Emotional Freedom Technique (Tapping)
- Healing Touch
- Reiki
- Hypnotherapy
- Massage Therapists
- Neuromuscular Massage Therapists
- Mindfulness Meditation
- Nutrition, Wellness and Sleep

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Other Alternative "Finds"

- Yoga
- Trauma-Specialist Psychiatrist
- Rolfing
- Work
- Open-Focused Brain
- Spire App (breathing)
- Muse App (meditation)
- Neuroscience
- BigMind (Zen)

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No-Longer a Hidden Metaphor

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THE PEW CHARITABLE TRUSTS

Balancing Harm Reduction with Patient Access to Pain Management Therapies

October 3, 2016

Cynthia Reilly, MS, BS Pharm
Director, Substance Use Prevention and Treatment Initiative
The Pew Charitable Trusts

Tools that Balance Safer Opioid Use and Patient Access

THE PEW CHARITABLE TRUSTS

Prescription Drug Monitoring Programs (PDMPs)

Patient Review and Restriction Programs (PRRs)

THE PEW CHARITABLE TRUSTS

91 percent of patients with a nonfatal overdose continue to receive opioids

But there's more to the story…

Annals of Internal Medicine ORIGINAL RESEARCH

Opioid Prescribing After Nonfatal Overdose and Association With Repeated Overdose
A Cohort Study

Marc R. Larochelle, MD, MPH; Jane M. Liebschutz, MD, MPH; Fang Zhang, PhD; Dennis Ross-Degnan, ScD; and A. Frank Wharam, MB, BCh, BAO, MPH

Background: Nonfatal opioid overdose is an opportunity to identify and treat substance use disorders, but treatment patterns after the overdose are unknown.

Objective: To determine prescribed opioid dosage after an opioid overdose and its association with repeated overdose.

Design: Retrospective cohort study.

Setting: A large U.S. health insurer.

Participants: 2848 commercially insured patients aged 18 to 64 years who had a nonfatal opioid overdose during long-term opioid therapy for noncancer pain between May 2000 and December 2012.

Measurements: Nonfatal opioid overdose was identified using International Classification of Diseases, Ninth Revision, Clinical Modification, codes from emergency department or inpatient claims. The primary outcome was daily morphine-equivalent dosage (MED) of opioids dispensed from 60 days before to up to 730 days after the index overdose. We categorized dosages as large (≥100 mg MED), moderate (50 to <100 mg MED), low (>0 to <50 mg MED), or none (0 mg MED). Secondary outcomes included time to repeated overdose stratified by daily dosage as a time-varying covariate.

Results: Over a median follow-up of 299 days, opioids were dispensed to 91% of patients after an overdose. Seven percent of patients (n = 212) had a repeated opioid overdose. At 2 years, the cumulative incidence of repeated overdose was 11% (95% CI, 14% to 20%) for patients receiving high dosages of opioids after the index overdose, 13% (CI, 10% to 21%) for those receiving moderate dosages, 7% (CI, 6% to 14%) for those receiving low dosages, and 8% (CI, 6% to 11%) for those receiving no medication.

Limitation: The cohort was limited to commercially insured adults.

Conclusion: Almost all patients continue to receive prescription opioids after an overdose. Opioid discontinuation after overdose is associated with lower risk for repeated overdose.

Primary Funding Source: Health Resources and Services Administration.

Ann Intern Med. 2016;164:1-9. doi:10.7326/M15-0038 www.annals.org

For author affiliations, see end of text.

This article was published online first at www.annals.org on 29 December 2015.

Treatment of chronic noncancer pain with prescription opioids has increased dramatically in recent decades (1–3). Opioid misuse and overdose have increased in parallel, and deaths due to prescription opioids quadrupled to 16 651 between 1999 and 2010 (4, 5). However, overdose deaths alone do not capture the full morbidity from prescription opioids. More than 300 000 patients visited an emergency department in 2008 due to nonmedical use of prescription opioids—more than double the total from 5 years earlier (6).

Presentation to an emergency department or hospital with a nonfatal opioid overdose is an opportunity to identify and refer patients who may be misusing opioids (7). Patients who report misuse of opioids and related adverse events are indications to discontinue long-term therapy (7, 8). However, patterns of treatment, including rates of continued prescribing, after an opioid overdose are unknown. Research suggests that opioid overdose is associated with substance use disorders or high opioid dosages (9, 10), but the association between opioid analgesia treatment after an overdose and subsequent overdose is unknown.

In this study, we sought to characterize opioid use after an overdose among patients receiving long-term opioid therapy for noncancer pain. We also aimed to determine whether patients who continued to receive prescription opioids after the index overdose switched providers and whether opioid dosage after an overdose was associated with risk for a subsequent overdose.

METHODS

Study Design and Data Source

We did a retrospective cohort study of persons having a nonfatal opioid overdose during an episode of long-term opioid use. We used the Optum database (Optum), comprising complete inpatient, outpatient, and pharmacy claims for patients from a large U.S. health insurer with members in all 50 states. We drew our cohort from 50 million commercially enrolled patients between May 2000 and December 2012 with a median follow-up of 15 months. We obtained study approval through the Harvard Pilgrim Health Care Institutional Review Board.

Patient Selection

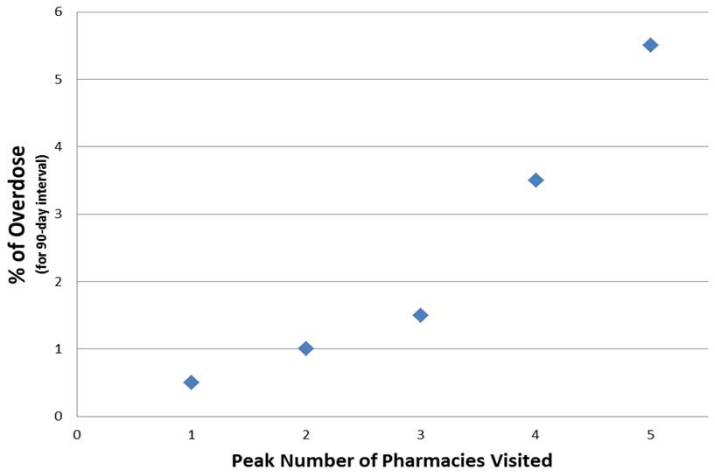
We identified 14 725 patients aged 18 to 64 years who had an index opioid overdose, defined as the first emergency department or inpatient claim with an

See also:
Editorial comment 62

© 2016 American College of Physicians 1

Larochelle MR, et al. *Ann Intern Med.* 2016;164 (1):1-9.

Multiple Provider Episodes Increase the Risk of Patient Harm



Adapted from Yang Z, et al. *J Pain.* 2015;16(5):445-53.

Optimizing Use of PDMP Data

In response to evidence of doctor shopping:

- 68 percent discussed it with the patient
- 32 percent screened for substance use disorders (SUD)
- 13 percent referred patient for SUD treatment

Only 6 percent discharged the patient from their care

http://digitalcommons.library.umaine.edu/cgi/viewcontent.cgi?article=1020&context=ant_facpub

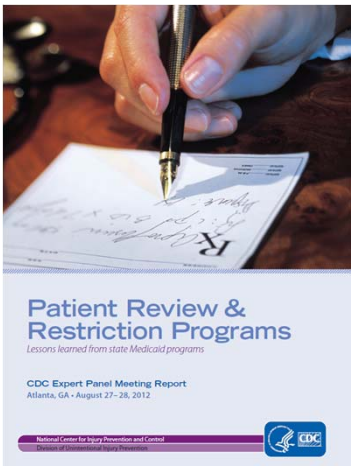
Innovative PDMP Practices to Improve Patient Care

Prescriber-set thresholds

Expanded patient data (e.g., overdose events)

PRR programs can:

- Reduce opioid usage to safer levels
- Save lives
- Reduce healthcare costs



https://www.cdc.gov/drugoverdose/pdf/pdo_patient_review_meeting-a.pdf

PRR characteristics and structures can:

- Impact effectiveness
- Support or inhibit improved patient care

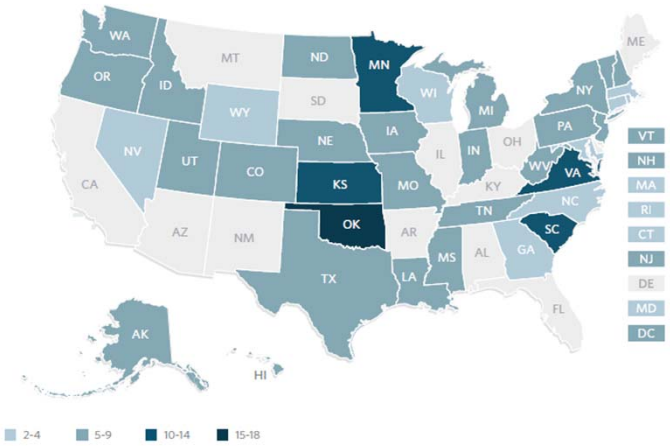
www.pewtrusts.org/prrreport

Example Criteria Used by Medicaid PRRs for Patient Enrollment

- Number of pharmacies
- Number of prescribers
- Number of controlled substance prescriptions
- Evidence of therapeutic duplication

www.pewtrusts.org/prrreport

Most States Use Multiple Criteria to Identify At-Risk Patients



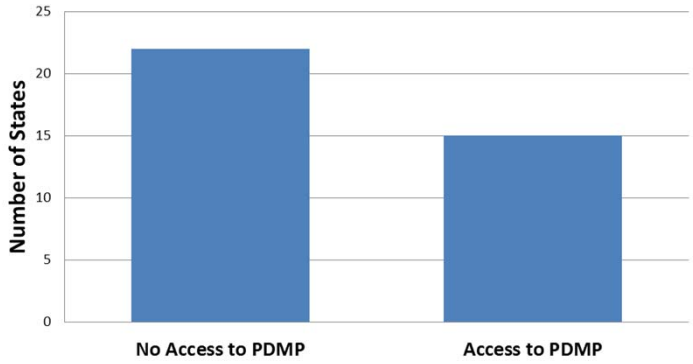
Note: These data represent 37 states and DC. This includes only states that responded to this survey question and operate a FFS PRR.

www.pewtrusts.org/prrreport

Over 50% of Medicaid PRR programs are not offering patients additional services to improve patient care.

www.pewtrusts.org/prrreport

Access to PDMPs May Improve Effectiveness of PRRs



Note: These data represent 37 states and DC. This includes only states that both responded to this survey question and operate a FFS PRR. "Other" represents state PRR programs that use the PDMP on a case-by-case basis or to aid open investigations. States can select more than one method in which they use the PDMP.

www.pewtrusts.org/prrreport

PRRs and Patient Outcomes

Intermediate or process measures indicate possible reduction in patient harms:

- Decreases in # pharmacies visited
- Decreases in # prescribers visited
- Reductions in prescription volume
- Decreased emergency room used

www.pewtrusts.org/prrreport

Conclusions

- PDMPs and PRRs are valuable tools to achieve harm reduction while ensuring patient access
- There are opportunities to enhance these tools and address barriers to their use
- Research is needed to better define impact and best practices for these programs

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http://www.pewtrusts.org/SubstanceMisuse

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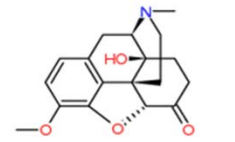
AMCP Opioid Symposium: Prescriber Perspectives

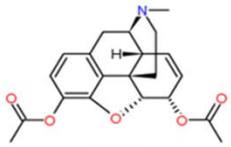
G. Caleb Alexander, MD, MS
Center for Drug Safety and Effectiveness
October 3, 2016

Protecting Health, Saving Lives—*Millions at a Time*

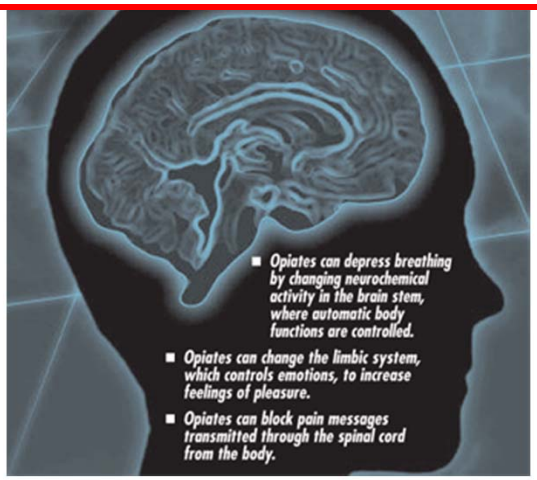
Similarities Between Illicit & Prescription Drugs



OXYCONTIN (OXYCODONE)



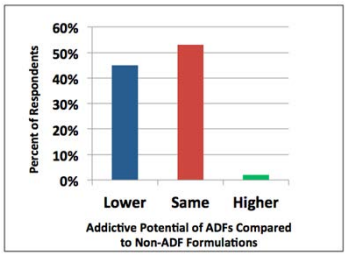
HEROIN



Dr. Nora D. Volkow, Director, (NIDA) National Institute of Health.

Abuse Deterrent Formulations

- Abuse-deterrent formulations target the known or expected routes of abuse, such as crushing in order to snort or dissolving in order to inject, for the specific opioid drug substance in that formulation
- Manufactures and FDA consider development of abuse-deterrent formulations a priority and are aggressively encouraging their development



Segal J. 2013.

CLINTON FOUNDATION

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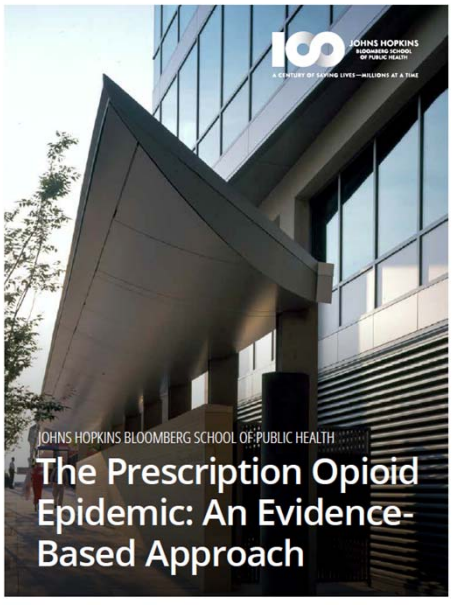
- Informing Evidence with Action
  - Scaling up evidence-based interventions; rapidly implementing and evaluating promising policies and programs
- Intervening Comprehensively
  - All along supply chain; clinic, community and addiction treatment settings; primary, secondary and tertiary prevention; creating synergies across different interventions
- Promoting appropriate & safe opioid use
  - Reducing overuse; focus on safe use, storage and disposal; optimizing use in accordance with best practices

5



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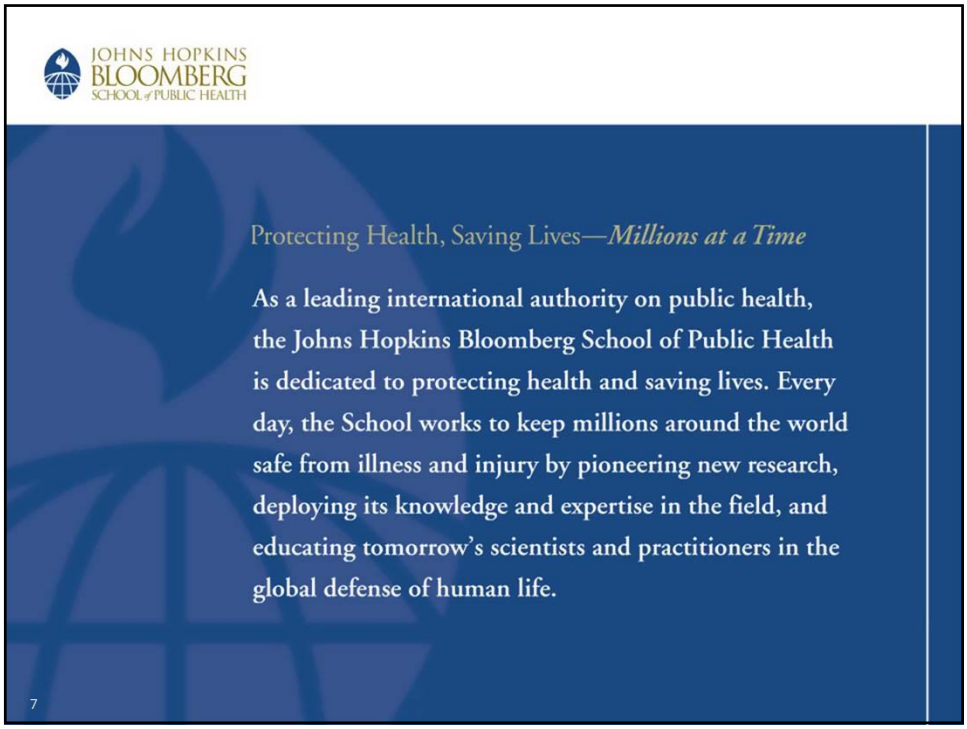
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Protecting Health, Saving Lives—*Millions at a Time*
As a leading international authority on public health, the Johns Hopkins Bloomberg School of Public Health is dedicated to protecting health and saving lives. Every day, the School works to keep millions around the world safe from illness and injury by pioneering new research, deploying its knowledge and expertise in the field, and educating tomorrow's scientists and practitioners in the global defense of human life.
7

PCSS MAT TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM
For Medication Assisted Treatment

PCSS O TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM
For Opioid Therapies

PCSS Projects

Kathryn L. Cates-Wessel
Executive Director, AAAP
PCSS-MAT and PCSS-O PI and Project Director

1

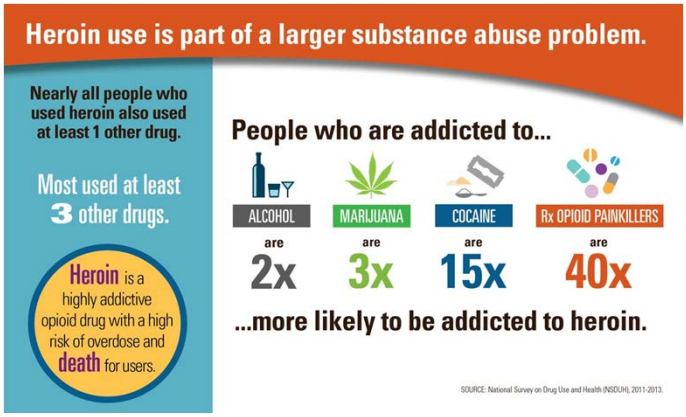
Educational Objectives

At the conclusion of this activity participants should be able to:

- Describe the two SAMHSA-funded projects PCSS-O and PCSS-MAT
- Navigate both PCSS-O and PCSS-MAT websites to find educational resources available to the public
- Utilize free mentoring/coaching program that allows primary care providers direct access to clinical experts in addiction psychiatry and addiction medicine
- Summarize data from key educational activities, identifying key barriers in treating patients using MAT therapies.

2

Substance Use Disorder Facts

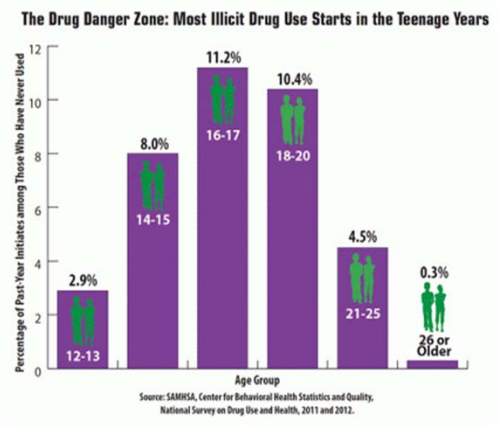


3

Image from CDC: http://www.cdc.gov/vitalsigns/heroin/infographic.html

Substance Use Disorder Facts
continued

- 20% of drug-related hospital admissions are due to heroin and opiates*
- In 2015, deaths from opioid/heroin overdoses overtook deaths from automobile accidents*



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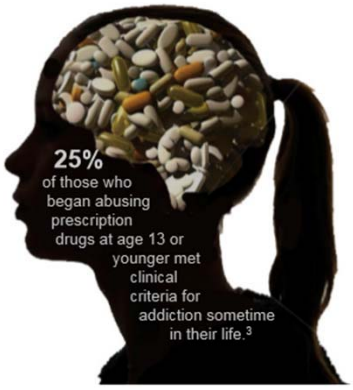
*Data from NIDA: https://www.drugabuse.gov/publications/drugfacts/drug-related-hospital-emergency-room-visits
**Data from DEA: https://www.dea.gov/divisions/hq/2015/hq110415.shtml
Image from NIDA: https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/preventing-drug-abuse-best-strategy

Prescription Drug Abuse: Young People at Risk

About 1 in 9 youth

or 11.4 percent of young people aged 12 to 25 used prescription drugs nonmedically within the past year.[3]



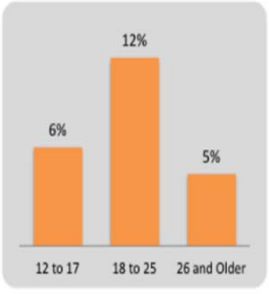
[1] Past Year Use
[2] Monitoring the Future Survey, 2011
[3] National Survey on Drug Use and Health, 2010

5

Image from NIDA: https://www.drugabuse.gov/related-topics/trends-statistics/infographics/prescription-drug-abuse-young-people-risk

Abuse of Prescription (Rx) Drugs Affects Young Adults Most

PAST-YEAR USE



In 2014, the nonmedical use of prescription drugs was highest among young adults.[2]

MOTIVATIONS FOR USE

Most young adults say they use Rx drugs to[3,4,5]

6

Image from NIDA: https://www.drugabuse.gov/related-topics/trends-statistics/infographics/abuse-prescription-rx-drugs-affects-young-adults-most

Abuse of Prescription (Rx) Drugs Affects Young Adults Most

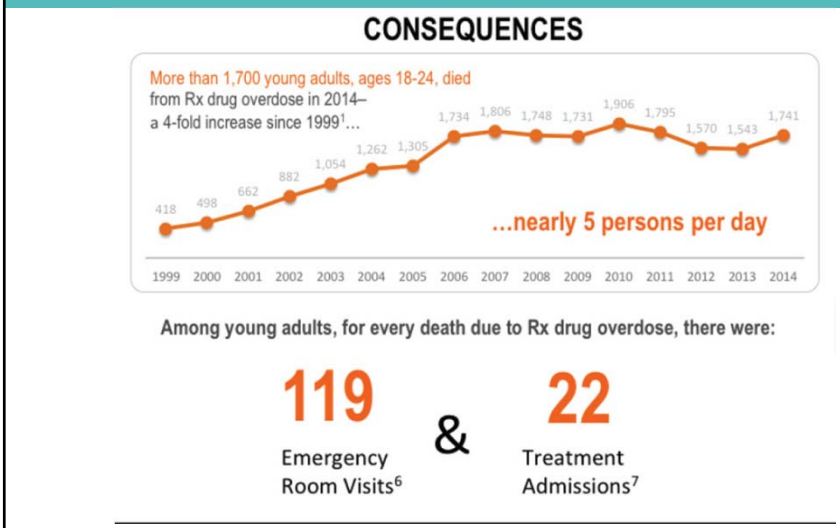


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Image from NIDA: https://www.drugabuse.gov/related-topics/trends-statistics/infographics/abuse-prescription-rx-drugs-affects-young-adults-most

What is PCSS-MAT?

The **Providers' Clinical Support System for Medication Assisted Treatment** is a three-year grant funded by SAMSHA in response to the opioid overdose epidemic.

PCSS-MAT is a national training and mentoring program developed to educate healthcare professionals on the use and availability of the latest pharmacotherapies.

8

PCSS-MAT Target Audience

- The overarching goal of PCSS-MAT is to make available educational and training resources on the most effective medication-assisted treatments to serve patients in a variety of settings, including primary care, psychiatric care, and pain management settings.

9

PCSS-MAT Training Modalities

PCSS-MAT offers no-cost training activities with CME to health professionals through the use of:

- **Webinars** (Live and Archived)
- **Online Modules**
- **Case Vignettes**
- **MAT Waiver Trainings**
- **One-on-one and Small Group Discussions—coaching for clinical cases**

In addition, PCSS-MAT offers a comprehensive library of resources:

- **Clinical Guidances and other educational tools**
- **Community Resources**
- **PCSS Listserv - Provides a "Mentor on Call" to answer questions about content presented through PCSS-MAT. To join email: pcssmat@aaap.org**

10

PCSS-MAT Mentoring Program

- Designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid addiction.
- A national network of trained providers with expertise in **medication-assisted treatment, addictions** and **clinical education**.
- 3-tiered mentoring approach allows every mentor/mentee relationship to be unique and designed to the specific needs of both parties.
- The mentoring program is available at no cost to providers.

For more information to request or become a mentor visit:
pcssmat.org/mentoring

11

PCSS-MAT Program Highlights

- 144 webinars and online modules with 40,747 training participants
- 309 Buprenorphine waiver trainings with 5,397 training participants
- Over 150 clinicians have participated in Small Group Discussions within the mentoring program (new initiative starting 2015)
- 55 mentors and 250 mentees and growing

Mentee Feedback
"I wanted to compliment my Mentor. I sent an email to him with a question…and within four hours I had not only his response but the input of four of his peers. This is a great service for those of us who are stretching the edges of what we would otherwise consider 'comfortable."
– William Roberts, MD, Medical Director, Northwestern Medical Center Comprehensive Pain Management

PCSS-MAT training data as of 8/30/2016

12

PCSS-MAT Waiver Trainings

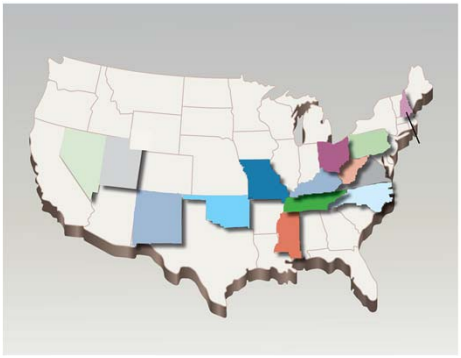
- 93 percent of trainees reported the buprenorphine waiver training would help them in their practice.
- 81 percent agreed or strongly agreed they planned to use buprenorphine in their practice.
- 65 percent said up to 10 percent of their patients were candidates for MAT.
- More than 90 percent rated the course and instructor highly.

13

PCSS-MAT 2015 evaluation summary

14 State Initiative: Connecting the Dots

As part of a pilot program, PCSS-MAT is working collaboratively with state medical societies, Governor's offices, medical schools, state chapters of key primary care professional organizations to train primary care providers in the use of medication assisted treatment in treating OUD.



States part of this pilot program:
Kentucky, Mississippi, Missouri, Nevada, New Hampshire, New Mexico, North Carolina, Ohio, Oklahoma, Pennsylvania, Tennessee, Utah, Virginia, and West Virginia

14

PCSS-MAT Contribution

- Work with SAMHSA and HRSA to provide support in outreach to the 14 states.
- Coordinate with states to define who should be included in the coalition—key organizations and individuals.
- Identify leaders from DATA 2000 partners and Steering Committee in each of 14 states to be local champions AND provide trainers to provide MAT waiver training.
- Facilitate discussions with all partners within each state and among DATA 2000 organizations and trainers.
- Create a website for sharing resources specifically for project.
- Create a state specific resource guide on MAT and local resources.
- Create a calendar of events to track activities .

P C S S MAT TRAINING

PROVIDERS' CLINICAL SUPPORT SYSTEM
For Medication Assisted Treatment

PCSS-MAT is a collaborative effort led by **American Academy of Addiction Psychiatry** in partnership with: **American Osteopathic Academy of Addiction Medicine**, **American Psychiatric Association**, **American Society of Addiction Medicine, Association for Medical Education and Research in Substance Abuse**, **American College of Physicians**, **American College of Emergency Physicians**, and **National Association of Drug Court Professionals**

For more information visit: www.pcssmat.org
For questions email: pcssmat@aaap.org

Twitter: @PCSSProjects

Funding for this initiative was made possible (in part) by Providers' Clinical Support System for Medication Assisted Treatment (grant nos. 5U79TI024697 and 1U79TI026556) from SAMHSA. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

PCSS O TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM
For Opioid Therapies

PCSS-O Overview

What is PCSS-O?

The **Providers' Clinical Support System for Opioid Therapies** is a three-year grant funded by SAMHSA in response to the opioid overdose epidemic.

Through education and colleague support, this national coalition of healthcare organizations is charged with creating no-cost trainings on the safe and effective use of opioids for treatment of chronic pain and opioid use disorders.

PCSS-O Target Audience

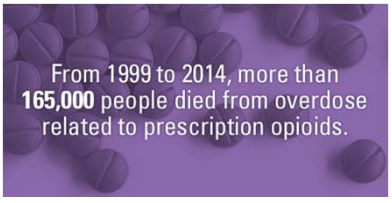
- The overarching goal of PCSS-O is to offer evidence-based CME trainings on the safe and effective prescribing of opioid medications in the treatment of pain and/or opioid addiction.
- Our focus is to reach providers and/or providers-in-training from diverse healthcare professions including physicians, nurses, dentists, physician assistants, pharmacists, and program administrators.

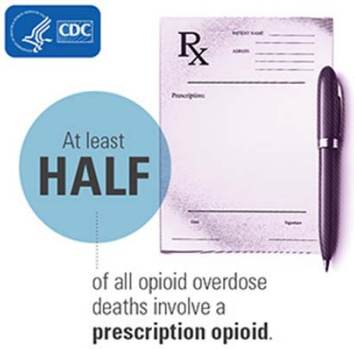
PCSS-O TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM For Opioid Therapies

19

Prescription Painkiller Misuse

- 4.3 million Americans engaged in non-medical use of prescription painkillers in the last month.
- Approximately 1.9 million Americans met criteria for prescription painkillers use disorder based on their use of prescription painkillers in the past year.





Data from SAMHSA: http://www.samhsa.gov/atod/opioids
Image from CDC: http://www.cdc.gov/drugoverdose/index.html
Image from CDC: http://www.cdc.gov/drugoverdose/epidemic/index.html

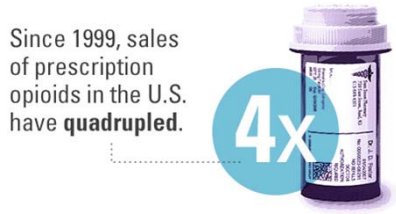
PCSS-O TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM For Opioid Therapies

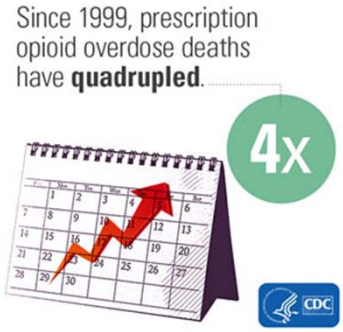
20

Prescription Painkiller Misuse

continued

- 1.4 million people used prescription painkillers non-medically for the first time in the past year.
- The average age for prescription painkiller first-time use was 21.2 in the past year.





Data from SAMHSA: http://www.samhsa.gov/atod/opioids
Image from CDC: http://www.cdc.gov/drugoverdose/index.html
Image from CDC: http://www.cdc.gov/drugoverdose/data/prescribing.html

PCSS-O TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM For Opioid Therapies

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PCSS-O Training Modalities

PCSS-O offers training activities with CME at no-cost to health professionals through the use of:

- **Live Webinars**
- **Archived Webinars**
- **Online Modules**

In addition, PCSS-O offers clinical resources and coaching:

- **Clinical Guidances and educational tools**
- **Coaching/peer support –one-on-one, small group discussions**
- **PCSS Listserv:** Provides an "Expert of the Month" to answer questions about content presented through PCSS-O project. To join email: pcss-o@aaap.org.

PCSS-O TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM For Opioid Therapies

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PCSS-O Colleague Support Program

- Offers general information to health professionals seeking guidance on evidence based practices in prescribing opioid medications and treating pain.
- Comprised of a national network of trained providers with expertise in **addictions, psychiatric co-occurring disorders and pain management.**
- Allows every colleague relationship to be unique and designed to the specific needs of both parties to help with clinical cases.
- Available at no cost.

For more information on requesting or becoming a mentor visit:

www.pcss-o.org/colleague-support

PCSS-O TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM For Opioid Therapies

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PCSS-O Program Highlights

- 26,497 webinar and online module participants (since July 2011)
- 5,640 PCSS-O phone app downloads
- 644 PCSS Listserv members
- 50 mentors involved
- 173 mentees participating
- 70 clinicians have participated in Small Group Discussions within the mentoring program

PCSS-O training data as of 8/22/2016

"I work at small rural health clinic with a nurse practitioner. We see many patients with chronic pain and substance abuse problems. We have very few resources available for our patients; no dietitian, limited counseling and psychiatry, etc. The Pain Tracker looks like a very useful tool and hopefully it will be available in EPIC soon. I have found the chain of emails on PCSS-O very interesting. It makes me feel less isolated. Thanks for all the helpful comments and handouts."
– Sheila Raumer, MD, PCSS Listserv Member

PCSS-O TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM For Opioid Therapies

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PCSS-O Webinar Participants

- 37 percent of participants are physicians
- 33 percent of participants are nurses
- Other disciplines include: counselors, pharmacists, social workers, and psychologists
- The largest majority or participants were psychiatrists (26%); family medicine (16%); internal medicine (12%); and pediatrics (10%).
- After taking trainings, 75% of participants said they were "confident" or "very confident" in their ability to safely prescribe opioids for pain.

PCSS-O 2015 evaluation summary

PCSS-O TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM For Opioid Therapies

PCSS-O TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM For Opioid Therapies

PCSS-O is a collaborative effort led by **American Academy of Addiction Psychiatry** in partnership with: **Addiction Technology Transfer Center**, **American Academy of Neurology, American Academy of Pain Medicine, American Academy of Pediatrics, American College of Physicians, American Dental Association, American Medical Association, American Osteopathic Academy of Addiction Medicine, American Psychiatric Association, American Society for Pain Management Nursing, International Nurses Society on Addictions,** and **Southeast Consortium for Substance Abuse Training.**

For more information visit: www.pcss-o.org
For questions email: pcss-o@aaap.org

Twitter: @PCSSProjects

Funding for this initiative was made possible (in part) by Providers' Clinical Support System for Opioid Therapies (grant no. 5H79TI025595) from SAMHSA. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

NABP: Update on Prescription Monitoring Programs

Philip P. Burgess, RPh, DPh, MBA
President, Philip Burgess Consulting, LLC

NABP®

NABP Mission Statement

The National Association of Boards of Pharmacy is an independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

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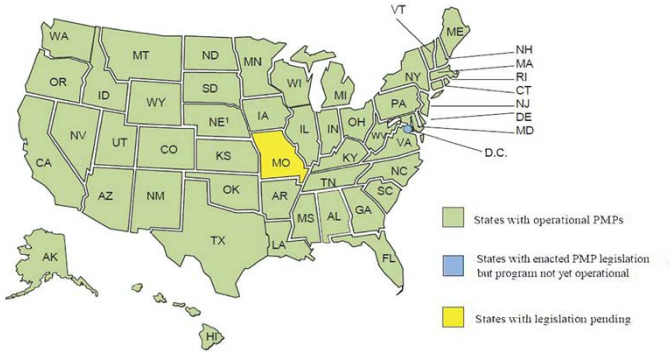
Status of State Prescription Monitoring Programs



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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Prescription Monitoring Programs (PMP): National Landscape

- 49 states have a functional PMP
- District of Columbia will be fully operational in Oct.
- Missouri – no authorizing legislation
- St. Louis County, MO is preparing to develop a county-wide PMP. St. Louis city and other counties might participate.

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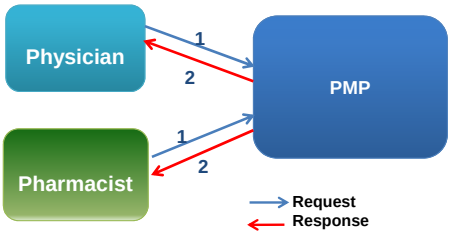
PMP Data Requested from State PMPs



- **State pays full cost, including fees for software, Internet, etc.**
- **No cost to pharmacy to report prescription data.**
- **No cost to prescriber or pharmacist to access patient information.**

Prescription Monitoring Programs (PMP): Prescription Data Collected

- Date of Dispensing
- Dispenser (pharmacy) identity
- Drug identity and quantity
- Patient identity
- Prescriber identity

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Good News about PMPs

- They are an effective tool.
- They operate in 49 states + DC (in Oct).
- They provide prescription drug information to treating health care professionals.
- Timeliness is improving (daily reporting required in 32 states).
- “One-click access” (via icon) is widely available and rapidly expanding.

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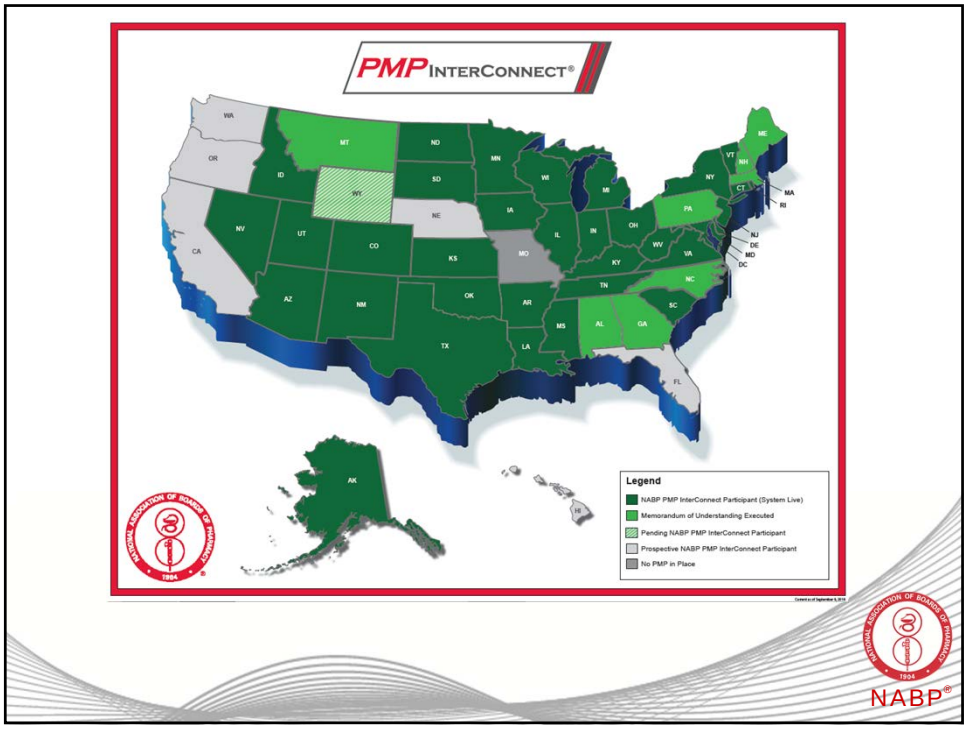
Main shortcoming of PMPs: Patients cross state borders

Solution – PMP InterConnect

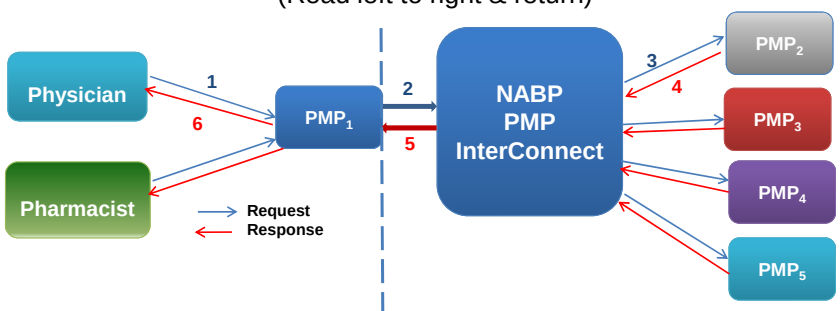
PMP INTERCONNECT®

NABP®



PMP Data Requested from Multiple PMPs

(Read left to right & return)



- State pays PMP costs as in previous slide
- No cost to prescriber or pharmacist
- State pays for state-side connection and maintenance on the connection.

- NABP pays for development, maintenance, enhancements, and transaction fees on PMP InterConnect
- No cost to state PMPs

Each State Controls All Access to Its Data

- Each state sets all of the “permissions” for that state with regard to the sharing of PMP data.
- A state may not be permitted by regulation to share with ALL states. Example: Iowa
- Only the state PMP administrator/director has access and controls these “permissions”.

Shortcomings of PMPs

Low utilization by health care

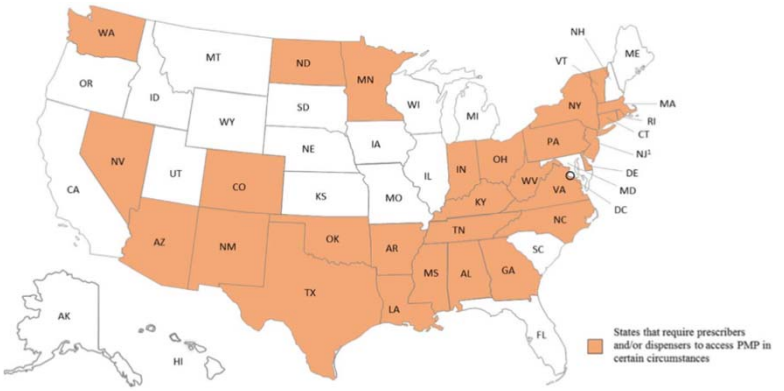
Solutions:

– Mandatory PMP registration (usually with license renewal)

– Mandatory PMP use (criteria vary)

– “One-Click Access”

States That Require Prescribers and/or Pharmacists to Access PMP Information in Certain Circumstances



[1]The New Jersey provision goes into effect on November 1, 2015.

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Future Steps to Increase Utilization of PMP Data

- Add additional states to PMP InterConnect.
- Promote “one-click access” to a patient’s PMP data within workflow for health care providers:
  - Health care systems or exchanges,
  - Electronic medical records,
  - Health information exchanges, and
  - Pharmacy software dispensing systems.

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Changing the way PMP data is used

- PMP Gateway® is an interface that give “one-click” access to a patient’s controlled substance prescription history from the PMP into health IT systems.
- Provides health IT systems a single access point to multiple state PMPs’ data via PMP Interconnect, thus saving healthcare providers the cost of individual integrations with each state PMP.
- PMP Gateway is live with implementations in 21 states
- Currently integrated with many leading EMR Platforms (EPIC, Cerner, QS1)
- Two states (OH, MA) are providing “one-click access” for prescribers and pharmacists in their state.

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Next goal – More “One Click Access” to PMP Data for Healthcare Providers

- No registration
- No extra usernames/passwords
- No data entry
- Better security
- No delay

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State PMP Challenges

- Getting the messages out
  - PMPs are effective – studies now show
  - PMPs are already working well in 49 states
  - States are able to experiment with innovations
  - Patient identity is best handled in smaller databases – local “investigation” can clarify.

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Potential Initiatives To Be Considered

- Require practitioners and pharmacists to access the PMP data PRIOR to prescribing or dispensing a controlled substance.
- Encourage patients to get smaller quantities of controlled substances for acute situations.
- Provide for medication therapy management by pharmacists for drug abuse treatment.

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Improving opioid safety: Insights from naloxone

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Harm Reduction Coalition

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New York, NY 10001

Undermanagement of overdose risk in chronic opioid treatment?

Original Research Article

Opioid Overdose History, Risk Behaviors, and Knowledge in Patients Taking Prescribed Opioids for Chronic Pain

Annals of Internal Medicine ORIGINAL RESEARCH

Opioid Prescribing After Nonfatal Overdose and Association With Repeated Overdose
A Cohort Study

Marc R. Larochelle, MD, MPH; Jane M. Liebschutz, MD, MPH; Fang Zhang, PhD; Dennis Ross-Degnan, ScD; and J. Frank Wharam, MB, BCh, BAO, MPH

- Roughly 20% of chronic pain patients receiving prescription opioids report lifetime history of overdose (Dunn et al., *Pain Med.* 2016)
- Over 90% of patients with non-fatal opioid overdose received a new opioid prescription, and 7% had a repeated overdose (LaRochelle et al., *Ann Intern Med.* 2016)

Naloxone as an opioid safety tool

- Significant concerns regarding safety of long-term opioid treatment for chronic pain
- Limitations of existing patient selection and risk mitigation strategies
- Challenge of balancing need for opioids with management of risks
- Role for naloxone in reversing opioid-induced respiratory depression
- Potential for naloxone to promote opioid safety discussions with prescribers & patients

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Naloxone overview

- FDA-approved opioid antagonist
- Quickly reverses opioid overdose and allows restoration of breathing
- Excellent safety profile
- Multiple formulations available (intramuscular, intranasal, autoinjector) – mix of branded & generic
- FDA labeling in newer formulations supports layperson administration

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4 Quadrants Framework for Naloxone Access

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Community-based Overdose Education & Naloxone Distribution (OEND)

- Pioneered in the late '90s by harm reduction programs reaching out-of-treatment heroin users
- Diverse settings: syringe exchange, health departments, recovery organizations, parents groups, drug treatment, drug courts….
- Largest evidence base: feasibility, acceptability, impact, cost-effectiveness
- Through June 2014, OENDs provided over 150,000 naloxone kits & received reports of 26,463 overdose reversals

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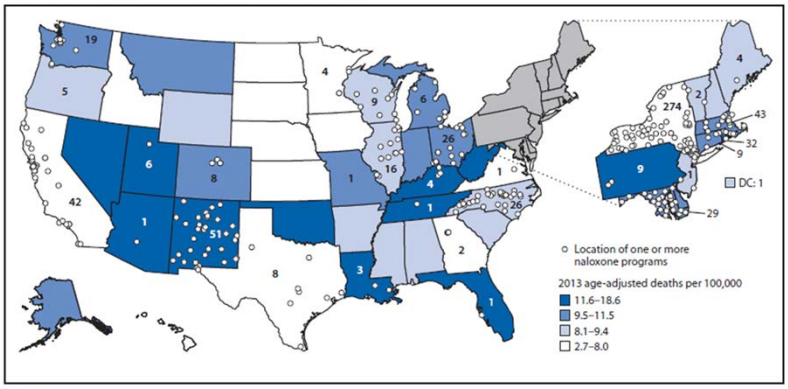
OEND programs as of June 2014

FIGURE 2. Number* and location of local drug overdose prevention programs providing naloxone to laypersons, as of June 2014, and age-adjusted rates† of drug overdose deaths§ in 2013 — United States



* Total N = 644; numbers on map indicate the total number of programs within each state.
† Per 100,000 population.
§ CDC, National Center for Health Statistics; Compressed Mortality File 1999–2013 on CDC WONDER Online Database, released January 2015.

Wheeler et al., *MMWR* 2015

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First responders & law enforcement

- Basic EMS (vs. Advanced) more common in rural areas (high overdose rates), but traditionally scope of practice has not allowed them to administer medications – now shifting to allow for naloxone
- Rapid uptake of naloxone by law enforcement (Department of Justice toolkit; grant support in Comprehensive Addiction & Recovery Act)

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Naloxone Prescribing

Influential early adopters of naloxone prescribing to at-risk patients:

- Project Lazarus in North Carolina integrated naloxone co-prescribing for patients receiving opioids into a broader overdose prevention and opioid safety initiative (Albert et al., *Pain Med. 2011)*
- The Veterans Administration Opioid Overdose Education and Naloxone Distribution programs have provided trained and naloxone to over 12,000 veterans as of December 2015 (Oliva et al., *Subst Abus.* 2016)

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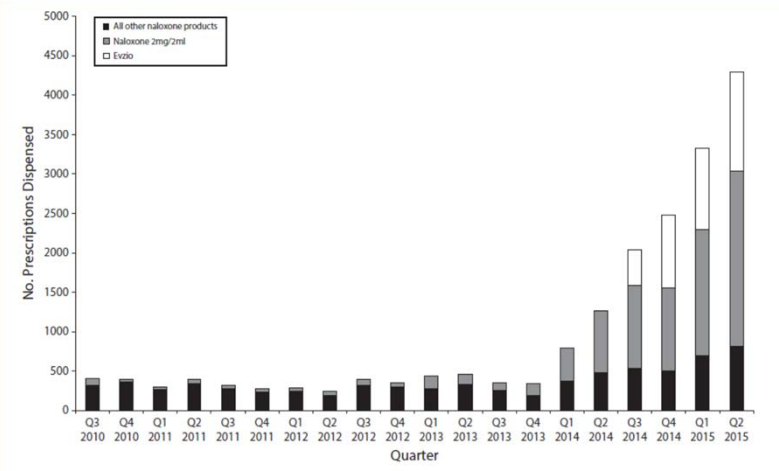
Naloxone Prescribing & Dispensing Rates Are Growing But Remain Low



Jones CM et al., *Am J Public Health* 2016

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Approaches to Naloxone Prescribing

- CDC Opioid Prescribing Guidelines: “consider offering naloxone when prescribing opioids to patients at increased risk for overdose”
- Prescribe to Prevent website with resources & tools for prescribers & pharmacists: http://prescribetoprevent.org/
- Opioid safety vs. overdose – San Francisco Department of Public Health naloxone co-prescription academic detailing

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Naloxone co-prescribing & opioid safety, San Francisco

Selected San Francisco Health Network clinics began co-prescribing naloxone to patients on opioids in 2013.

“I had never really thought about [overdose] before…it was more so an eye opener for me to just look at my medications and actually start reading [about] the side effects, you know, and how long should I take them…I looked at different options, especially at my age.”

—San Francisco patient[17]

Offering a naloxone prescription can increase communication, trust and openness between patients and providers.

“By being able to offer something concrete to protect patients from the danger of overdose, I am given an opening to discuss the potential harms of opioids in a non-judgmental way.”

—San Francisco primary care provider[18]

Source: SFDPH naloxone detailing provider’s guide

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Naloxone co-prescribing & health outcomes (Coffin et al., *Ann Intern Med.* 2016)

- Naloxone prescribed to 38.2% of 1985 patients on long-term opioid treatment in SF public primary care clinics
- 47% fewer emergency department visits among patients receiving naloxone after 6 months
- 63% fewer emergency department visits among patients receiving naloxone after 6 months
- Patients on higher opioid doses & those with prior overdose more likely to receive naloxone

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Pharmacy access to naloxone

- Naloxone remains a prescription drug, but can be dispensed by pharmacists under some circumstances
- Pharmacy access to naloxone possible in many states under standing orders or collaborative practice agreements
- Large chains & independent pharmacies moving quickly in many states
- On-going dialogue about whether naloxone could/should be over-the-counter

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Conclusions & Implications

- Naloxone prescribing can improve opioid safety
- Unresolved questions over patient selection:
  - higher opioid doses?
  - concomitant benzodiazepines?
  - mental health and/or substance use disorder diagnosis?)
- Clarity around coverage & formulary placement
- Reimbursement for third-party administration
- Considerations on dose and formulation

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Questions

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Pharma, Payers and Physicians: Partnering to Advance Pain Treatment and Address Opioid Abuse

Tracy J. Mayne, PhD.
Head of Medical Affairs Strategic Research
Purdue Pharma L.P.

Three Projects

Pharma, Payers and providers have common goals:

- Prevent opioid abuse and over use
- Adequately treat chronic pain and improve patients' lives

Three projects with 2 goals

- Goal 1: Predictive algorithm
  - An atlas of extended-release opioid (ERO) prescribing
  - Define how cost unfold around first episode of opioid abuse
- Goal 2: Wearable Health Technology
  - AppleWatch and pain app for the treatment of chronic pain

2

Atlas of Extended-release Opioid (ERO) Prescribing

Objective

Exhaustively characterize the treatment patterns of all non-cancer patients initiating an extended-release opioid from April 1, 2011 to September 30, 2013

Database

- Truven database (n=98 million), nationally representative
- Longitudinal insurance claims: Employers, commercial insurance, Medicare and Medicaid
- Care settings: Outpatient, inpatient, emergency room, rehabilitation, pharmacy

Sample

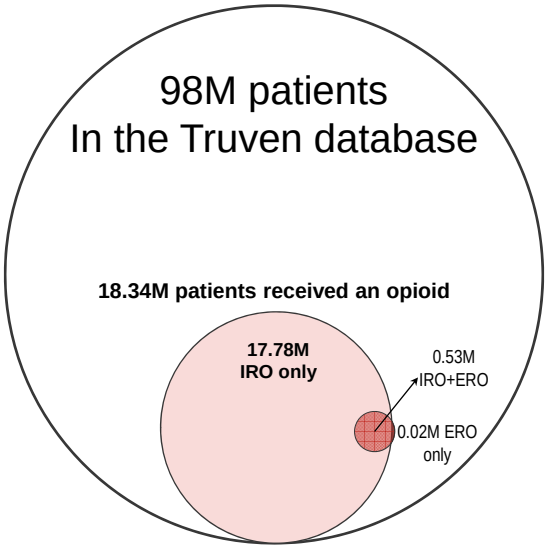
- Inclusion criteria:
  - Patients filling a first extended-release (ER) opioid prescription 1/1/2011 - 9/30/2013
  - No ER opioid prescription before 1/01/2011 (incident users)
  - 3 months of continuous eligibility before initial ER opioid prescription
  - 2 years of continuous eligibility after index ER opioid prescription
- Exclusion criterion: Cancer diagnosis

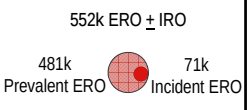
Methods

- Date of first ER opioid prescription is the index date
- Episode of use allows gaps of ≤60 days
- >60 day gap becomes a new episode of use
- 90 day titration period allowed for long-term users
- Measures
  - ERO and IRO
  - Duration of use
  - Dose change

3 ERO=extended-release opioid, IRO= immediate release opioid.

Patients Receiving Opioids

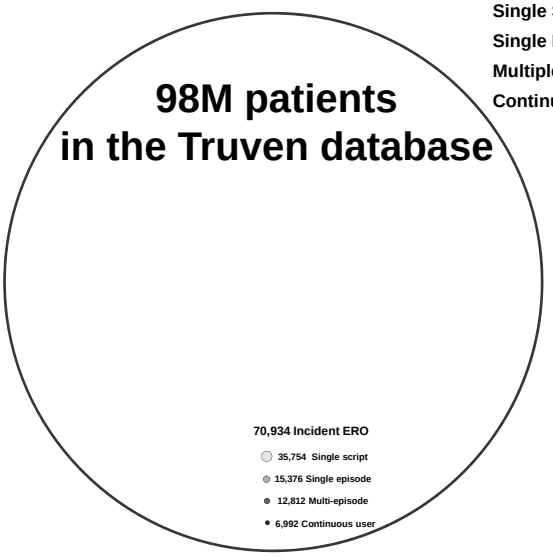


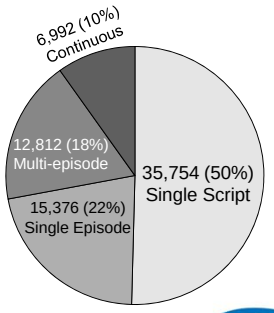


4 ERO=extended-release opioid. IRO = immediate release opioid.

Incident ERO Patients

Single Script: One ER opioid script ≤30 days
Single Episode: ≥2 ER opioid scripts, no gap >60 days
Multiple Episode: ≥2 opioid episodes, >60 day gaps
Continuous users: 2 years of use, no gaps >60 days





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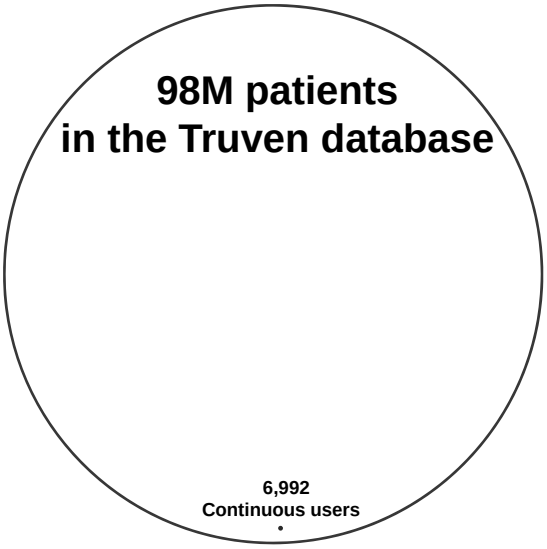
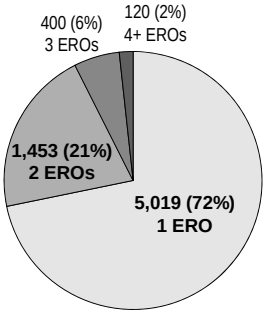
Incident ERO Continuous Users: 2 Years, No Gaps >60 Days





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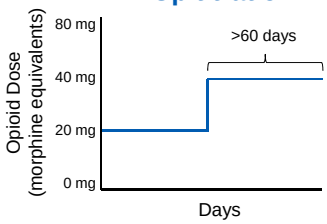
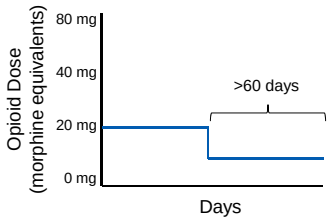
Defining Dose Changes: Titration and Excursion

Titration

Up titration

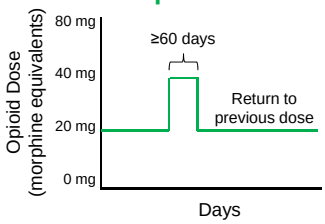


Down titration

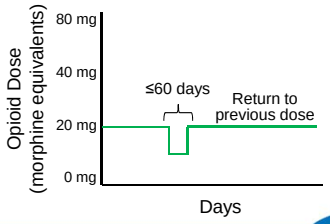


Excursion

Up excursion



Down excursion



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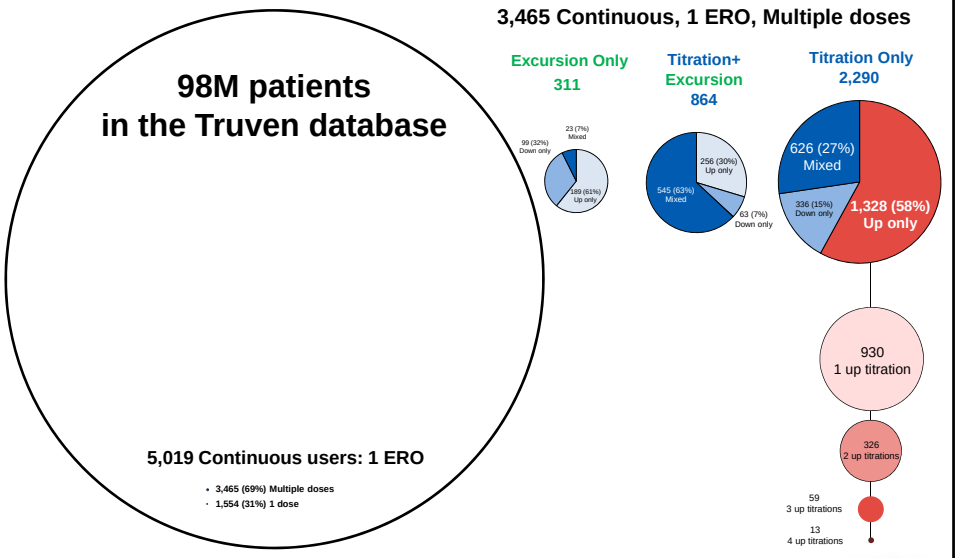
Incident ERO Continuous Users: 2 Years, No Gaps >60 Days



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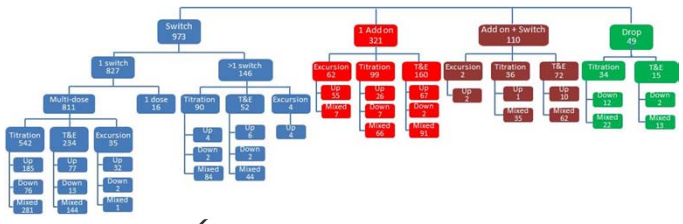
Incident ERO Continuous Users, 2 EROs

98M patients in the Truven database



1,453 Continuous users, 2 EROs

Potential Payer Use

- What does “usual prescribing” look like?
- What do outlier patients look like?
- What do outlier prescribers look like?
- Could we use these data to identify potential misuse/abuse
  - Escalation patterns
  - Futility analysis
  - Pill collecting

Costs of Abuse

Objective

Quantify and characterize the incremental costs of opioid abuse/dependence/overdose/poisoning from January 1, 2012 to March 31, 2015

Database

- Optum database (n=6.6 million)
- Longitudinal insurance claims: Employers, commercial insurance, Medicare supplemental
- Care settings: Outpatient, inpatient, emergency room, rehabilitation, pharmacy

Sample

- Inclusion criteria:
  - Ages 18-64
  - Continuous non-HMO eligibility
- Exclusion criterion
  - Methadone or buprenorphine (other than transdermal) use during baseline
  - ICD-9 code indicating remission (abuser cohort)
  - Patients with a single outpatient diagnosis claim of substance dependence, who had received a prescription opioid from a provider in the previous 6 months

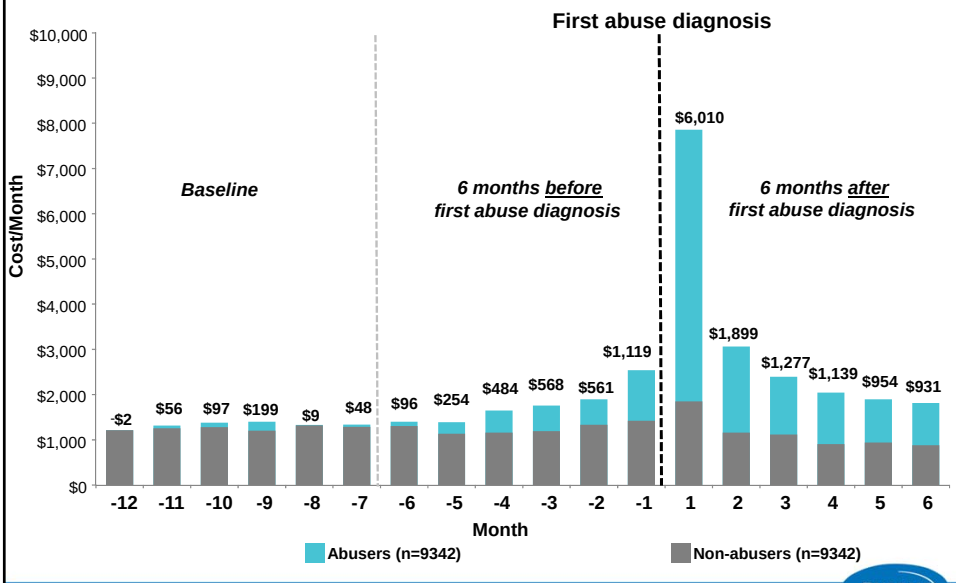
Methods

Two cohorts identified for propensity score matching

- Abusers
  - ICD-9-CM codes for opioid abuse, dependence, or overdose/poisoning
  - Index date: date of first abuse diagnosis
- Non-Abusers
  - No diagnosis for opioid abuse/dependence/poisoning/overdose
  - Index date: date of a randomly selected medical claim
- Measures
  - Health care cost by place of service (ie inpatient, outpatient/other, emergency)
  - Top diagnoses contributing to the excess medical costs among abusers

11

Excess Health Care Costs



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Excess Costs Before Diagnosis

Total health care costs	**$3,084**
Inpatient costs (total)	**$729**
Alcohol dependence syndrome	$89
Other diseases of lung	$82
Drug dependence (excluding opioids)	$67
Vascular insufficiency of intestine	$26
Curvature of spine	$25
Other cellulitis and abscess	$24
Emergency department costs (total)	**$1,431**
Other symptoms involving abdomen and pelvis	$69
General symptoms	$52
Diseases of pancreas	$46
Septicemia	$33
Other cellulitis and abscess	$32
Symptoms involving respiratory system and other chest symptoms	$31
Rehabilitation facility costs (total)	**$274**
Drug dependence (excluding opioids)	$152
Alcohol dependence syndrome	$102
Episodic mood disorders	$11
Certain adverse effects not elsewhere classified	$3
Adjustment reaction	$2
Nonspecific findings on examination of blood	$2
Outpatient/other costs (total)	**$584**
Drug dependence (excluding opioids)	$183
Alcohol dependence syndrome	$123
Other and unspecified disorders of back	$75
Other symptoms involving abdomen and pelvis	$37
Multiple myeloma and immunoproliferative neoplasms	$28
Prescription drug costs	**$66**

- $3,084 in the 6 months **before** 1st diagnosis
- Drivers of excess cost
  - Non-opioid drug abuse & dependence
  - Alcohol abuse & dependence

Excess Costs After Diagnosis

Total health care costs	**$11,726**
Inpatient costs (total)	**$2,880**
Drug dependence (opioids)	$700
Drug dependence (excluding opioids)	$242
Alcohol dependence syndrome	$173
Complications peculiar to certain specified procedures	$69
Intervertebral disc disorders	$68
Spondylosis and allied disorders	$60
Emergency department costs (total)	**$2,306**
Poisoning by analgesics (opioids)	$189
Drug dependence (opioids)	$135
Other diseases of lung	$125
Other symptoms involving abdomen and pelvis	$50
Poisoning by other and unspecified drugs and medicinal substances	$45
Poisoning by analgesics antipyretics and antirheumatics (excluding opioids)	$42
Rehabilitation facility costs (total)	**$2,324**
Drug dependence (opioids)	$1,077
Drug dependence (excluding opioids)	$607
Alcohol dependence syndrome	$339
Anxiety, dissociative and somatoform disorders	$19
Depressive disorder, not elsewhere classified	$14
Other ill-defined and unknown causes of morbidity and mortality	$13
Outpatient/other costs (total)	**$3,906**
Drug dependence (opioids)	$1,487
Drug dependence (excluding opioids)	$1,026
Alcohol dependence syndrome	$398
Nondependent Abuse of drugs (excluding opioids)	$86
Spondylosis and allied disorders	$75
Prescription drug costs	**$310**

- $11,726 in the 6 months **after** 1st diagnosis
- Drivers of excess cost
  - Opioid dependence & poisoning
  - Non-opioid drug abuse & dependence
  - Alcohol abuse & dependence
- Opioid abuse/dependence costs ≈ Non-opioid + alcohol abuse/ dependence costs
- **Overall cost drivers:**
  - 34% Opioid abuse/dependence/overdose
  - 27% Non-opioid drug and alcohol abuse/ dependence/overdose
  - 39% Without a specific abuse/ dependence/overdose ICD-9 code

Potential Payer Use

Could economic and diagnosis criteria be used to identify abuse before it happens (predictive algorithm)?

- Increase in healthcare resource use
- Diagnosis of other substance abuse/dependence/overdose
- Non-specific ER symptoms (Drug seeking? Constipation?)

Limitations of claims data analyses

- Analysis relies on the accuracy of claims data; miscoding in the underlying data could affect results
- Undiagnosed opioid abusers may be included in the “non-abuser” cohort, which may understate the actual excess cost differential between abusers and controls without diagnosed opioid abuse
- The study focuses on the commercially insured population, thus the results may not generalize to other populations

Wearable health technology to treat chronic pain

Can wearable health technology improve care AND decrease cost?

Wearable/Remote Health Technology

Sensors measure biometric and behavioral data, providing immediate feedback

Wristband

Simple
Movement

Multi-channel
Movement
Heartrate
GPS
Self-report

Patch

Multi-channel
Sweat
Sweat chemistry
Blood
Blood chemistry

Lens

Multi-channel
Tear chemistry

Garment

Multi-channel
EKG
Respirometer
EMG
Movement
GPS
Skin temp
Body measure/fat
Sweat
Sweat chemistry

Implant

Multi-channel
Blood chemistry

Drug delivery

Bottle Cap

Simple
Drug adherence

Pill Cam/Sensor

Simple
GI Chemistry
GI visual

Require intermediary device for data upload

18

This is not the Future, it is Now

$85-
$250

$190-
$1050

$200-
$650

sano

Close to market

Google
NOVARTIS

Close to market

ATHOS

$400-
$550

Medtronic

Close to market

Sensor + piump
$6500-
$7500

MEMSCAP
The Power of a Small World™

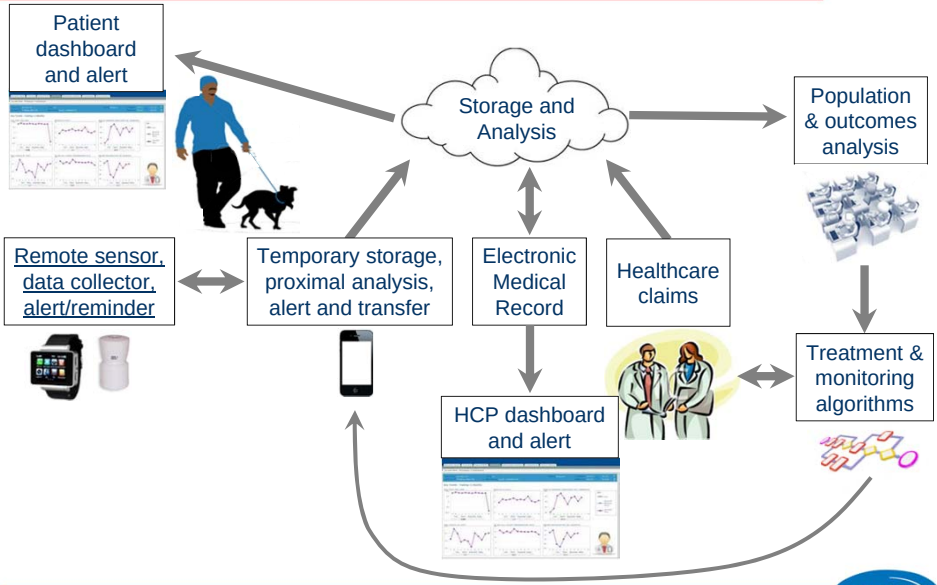
$30

Pillcam

$500

PURDUE

Overarching concept



PURDUE

Example: Chronic Pain Disease Management

Data collection
Physical activity
Sleep movement
GPS location
Medication utilization/adherence
Patient-reported pain
Patient-reported depression
Health-related quality of life

Patient dashboard

20% increase in pain last week
30% decrease in physical activity
Early morning waking
Pain spikes at 7:00 AM
ERO at 7:00 AM and 5:00 PM
Rescue IR at 8:00 AM

HCP dashboard

Nurse alert: Pain ↑, physical activity ↓
Early morning waking
Pain spikes at 7:00 AM
ERO at 7:00 AM and 7:00 PM
Nurse alert: Increase in IR

Take ERO at 10 AM & 10 PM or
Switch to QD ERO
Physical therapy: morning stretches
Monitor IR use

Wearable Device and Pain App Study Design

Objective	Design, implement, and study the use of a health monitoring device + pain app, and evaluate their impact on outcomes in chronic pain patients treated in a multi-disciplinary pain program (MPP)
Design	Prospective, non-randomized, controlled, observational trial
Population	Intervention: 200 chronic pain patients treated at a MPP + wearable device and Pain App Historic control: 200 chronic pain patients treated at a MPP in previous year Prospective control: 400 chronic pain patients not enrolled in MPP (SoC) propensity score matched to intervention group
Inclusion	• Enrolled in the Multidisciplinary Pain Program and complete the initial 3-day seminar; • 18 years of age or older; • Persistent pain for at least six months; • Pain-related altered functional, vocational, and/or psychosocial behaviors
Endpoints	• Visual Analog Pain Scores • Physical activity (fitness tracker) • Disability and physical function (Oswestry Disability Index) • Depression (PHQ-2, PHQ-8) • Calculated morphine equivalents • Medication Adherence • Sleep Quality • Weight • HCRU and cost

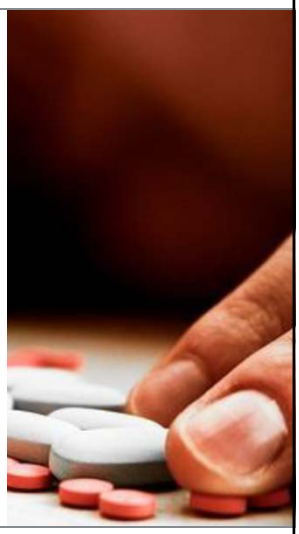
Overall Summary

- Partnering with payers and providers, use these findings to develop a predictive algorithm that identifies patients with abuse potential and/or in the early stages of abuse
- Partnering with integrated disease network to develop wearable health technologies to improve care (including lower opioid use) and decrease cost

OPTUMRx

Total Opioid Management

David Calabrese, R.Ph., MHP
Chief Pharmacy Officer



Opioid abuse: A national epidemic and public health emergency

OPTUMRx

4.5 Million Addicts Estimated U.S. citizens addicted to prescription opioids[1]

44 Daily Deaths Americans die **every day** from an Rx opioid overdose[2]

Record increase in **opiate-related deaths** in U.S. from 2013 – 2014[3] **14%**

Annual U.S. Societal Costs of **Rx opiate abuse**[4] **$56 Billion**

1. Annual Rev of Pub Health 2015; 36: 559-574; 2. US Dept of HHS 2016; 3. MMWR January 1, 2016 / 64(50);1378-82; 4. Pain Medicine 2014; 15: 1450–1454

Disheartening statistics

Consumed in the U.S.

80% of the world's supply of **ALL Rx opioids**

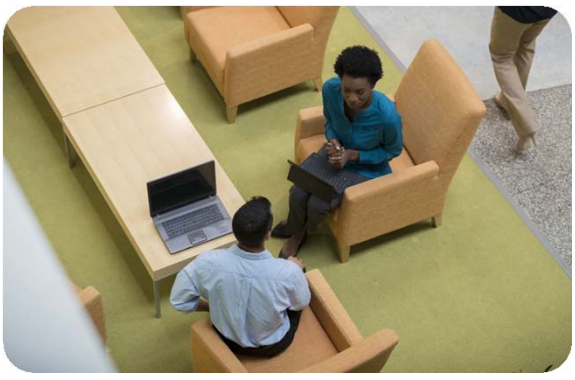
99% of the world's supply of hydrocodone

81% of the world's supply of oxycodone

Source: National Institute on Drug Abuse. May 2014.

What systematic reviews of the cumulative opioid evidence suggests

- Effectiveness is limited
- Significant side effects
- Risks are substantial
- Effects on human function are very small



1. CMAJ. 2006; 174
2. Clin J Pain. 2008; 24
3. Cochrane Database Syst Rev. 2010; 372

Why Optum is uniquely position to lead in this area

OPTUMRx

OPTUMRx® + OPTUM®

People Technology Data Action

Total Opioid Management: Where We Are Headed

"Five for Life"

Prevention & Education | **Minimizing Early Exposure** | **Provider Surveillance** | **ID & Support At-Risk Populations** | **Manage Afflicted Population**

Prevention & Education

Patient

- National & local public awareness campaigns
- 1st-fill patient education
- “Take-Back” programs

Provider

- Targeted provider education (e.g., SCOPE)
- Ac tively promoting routine Prescription Drug Monitoring Program adoption/use

Organizational

- Revisiting key internal operational functions (e.g., opiate dispensing via mail)

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Minimizing Early Exposure

Concurrent DUR Edits

- Concomitant therapy (e.g., opiate + benzodiazepine)
- Tighter refill window limits (90-95%)
- Pregnancy screening

Expanded UM Edits

- Much tighter 1st-fill QLs on all opioids: brand & generic; short- and long-acting
- Limited subsequent fills and quantities w/o PA
- Age edits (children and elderly)
- Morphine-milligram equivalent dosing edits
- More aggressive and expanded PA limits, particularly in opioid naïve patients
- Specialist prescribing limits (e.g., dentist)
- Urine testing reqs w/ chronic usage

OPTUMRx

Provider Surveillance

Prescriber

- Enhanced monitoring and restrictions on providers with state-level prescribing sanctions
- Opiate prescriber ‘scoring’ system
- Specialty-level provider profiling
- More proactive collaboration and data sharing with state & federal regulatory & licensing bodies

Pharmacy

- Advanced analytics to identify disproportionate opiate dispensing patterns at pharmacy level
- Enhanced auditing

OPTUMRx

ID & Support At-Risk Populations

- Sophisticated patient-level analytic assessment; risk stratification & scoring
- Multidimensional R-DUR monitoring & intervention
- Substance abuse support ‘hot-line’
- Behavioral Health risk assessment
- Medication Assistance Treatment (MAT) education and referral
- Pain Management referral and CM support

OPTUMRx

Manage Afflicted Population

- Utilizing historic medical/pharmacy claims and EMR data to flag pts in our claims system with recent or past history of OD or SUD treatment
- Pharmacy and/or prescriber 'lock-in' programming
- Post-discharge relapse prevention support
- Medication Assistance Treatment
- Restricted access (via PA) to opiates in those actively undergoing opiate abuse treatment
- Physician guidance on proper naloxone prescribing

OPTUMRx

OPTUMRx

FORUM2016
TRANSFORMING HEALTH CARE TOGETHER

We are ALL accountable…

…and thus ALL need to be part of the solution.

Balancing Access and Harms in Opioid Use for Managing Acute and Chronic Pain

PCORI's Commitment to Improving the Evidence Base

Penny Mohr, MA, Senior Program Officer, Improving Healthcare Systems, PCORI

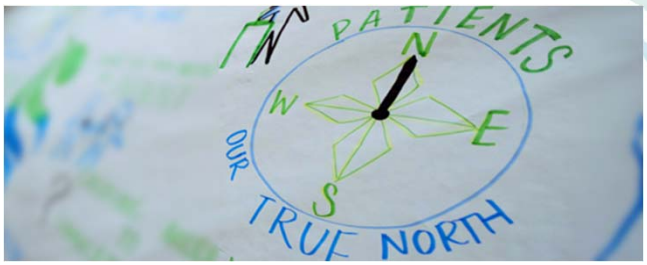
October 3, 2016

pcori

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

About Us

- An independent research institute authorized by Congress in 2010 and governed by a 21-member Board of Governors representing the entire healthcare community
- Funds comparative clinical effectiveness research (CER) that engages patients and other stakeholders throughout the research process
- Seeks answers to real-world questions about what works best for patients based on their circumstances and concerns



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PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Our Mission and Strategic Goals

PCORI helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from **research guided by patients, caregivers, and the broader healthcare community.**

Our Strategic Goals:

- Increase quantity, quality, and timeliness of useful, trustworthy research information available to support health decisions
- Speed the implementation and use of patient-centered outcomes research evidence
- Influence research funded by others to be more patient-centered

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Why is this topic important to patients and other key stakeholders?

- Opioid abuse resulted in more than 18,000 deaths from prescription opioids in 2014 (NIH, 2015)
- Pain advocacy community has expressed concerns about the unintended harms to pain sufferers that may occur by restricting access to opioids

Any policies in this area must strike a balance between our desire to minimize abuse of prescription drugs and the need to ensure access for their legitimate use.

- **What stakeholder groups have identified this as an important question?**
  - Payers; specifically, National Association of State Medicaid Directors
  - Friends and family members who lost someone to prescription opioid abuse; patients with chronic pain; worker's compensation organizations; state and federal policymakers

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Abundance of Evidence Gaps

- Wide variation among states in opioid prescribing rates; indicating a lack of consensus about when to prescribe opioids (CDC, 2016).
- Little evidence exists on how to improve safe prescribing of opioids (Dy et al, 2016)
- No studies examined the comparative effectiveness of opioids vs. non-opioid therapies (pharmacological or non-pharmacological) for outcomes >1 year
- Little available evidence on the effectiveness of dose escalation, withdrawal/tapering strategies, short/long acting opioids
- A number of strategies targeted to providers and/or patients to promote safe opioid prescribing have been developed but not rigorously evaluated (HHS, 2014).
- Guidelines recommend use only when alternatives are ineffective (CDC, 2016; Dy et al., 2016).

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PCORI Can Add to the Funding and Policy Landscape

- **Broad set of initiatives across a number of agencies**
  - The President's Budget
  - DHHS Secretary's Initiative
  - Trans-Agency Initiative, IOM National Pain Strategy
  - CDC Guideline for Prescribing Opioids for Chronic Pain
  - FDA Action Plan

  These initiatives are being rolled out rapidly without strong evidence.

- **Research agenda just being developed**
  - Federal Pain Research Strategy Committee
  - NIH Pathways to Prevention

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Evaluation of a Health-Plan Initiative to Mitigate Chronic Opioid Therapy Risks

Potential Impact

- Could determine best practices to stem the epidemic of opioid addiction and overdose that results from long-term use in treating chronic pain

Engagement

- Patients and advocates make up a patient advisory panel that will guide the investigators

Methods

- Large patient survey and evaluation of health outcome data

Evaluates a health-plan initiative to reduce risks of long-term opioid use for chronic pain. The initiative includes reduced prescribing of high opioid doses and increased care planning and monitoring of chronic opioid therapy patients. The study will determine if the initiative influenced pain outcomes, patient-reported opioid benefits and problems, and opioid-related adverse events.

Michael Von Korff, ScD,
Group Health Cooperative
Seattle, WA

Improving Healthcare Systems, awarded December 2013

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PCORI Targeted Opioid Initiatives

Title	Actual or Expected Award Date	# of Projects	Budget
Treatment Strategies for Managing and Reducing Long-Term Opioid Treatment for Chronic Pain (awarded)	July 2016	2	$21M
Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Non-cancer Pain	May 2017	Up to 8	Up to $30M
Treatment Strategies for Managing and Reducing Long-Term Opioid Treatment for Chronic Pain (Re-release)	August 2017	TBD	Up to $19M

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8

Clinical Strategies for Managing and Reducing Long-term Opioid Use for Chronic Pain

- **Research Questions**
  - » Among patients with chronic noncancer pain on moderate/high-dose long-term opioid therapy, what is the comparative effectiveness of strategies for reducing/eliminating opioid use while managing pain?
  - » Among patients with chronic noncancer pain on moderate/low-dose long-term opioid therapy, what is comparative effectiveness and harms of strategies used to limit dose escalation?
- **Goal:** manage patient pain first while also reducing risks and harms of long-term opioid use

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9

Comparative effectiveness of patient-centered strategies to improve pain management and opioid safety for Veterans

Potential Impact

- Could provide evidence to support the use of replicable strategy to improve pain and reduce opioid use

Comparators

- telecare collaborative medication management led by clinical pharmacist versus interdisciplinary pain management team emphasizing non-pharmacological alternatives

Design

- RCT of 1400 primary care patients at 9 VA sites receiving moderate to high-dose opioids.

Compares two systems of care strategies, which differ substantially in comprehensiveness and resource intensity, to improve pain and reduce opioid use among Veterans. This includes a sub-study among patients on high-dose chronic opioid therapy to compare tapering with or without buprenorphine rotation.

Erin Krebs, MD, MPH,
University of Minnesota
Minneapolis/St. Paul, MN

Awarded 2016

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Strategies to improve safe opioid prescribing in primary care among patients with acute or chronic non-cancer pain

- **Research Questions**
  - » What is the comparative effectiveness of different payer or health system strategies that aim to prevent unsafe opioid prescribing while ensuring access to non-opioid methods for pain management with the goal of reducing pain and improving patient function and quality of life outcomes, while reducing patient harm?
  - » What is the comparative effectiveness of different patient and provider facing interventions that facilitate improved knowledge, communication and/or shared decision making about the harms and benefits of opioids and alternative treatments on prevention of unsafe prescribing and improved patient outcomes?

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Anticipated Challenges In Sustainability and Adoption

- How do we adapt models that have proven to be successful in highly-integrated systems into more fragmented care delivery?
- Among these complex, multi-component systems approaches, what is the most efficient way to meet the dual goals of improving pain management and reducing unsafe opioid use?
  - – Which aspects of these strategies are the most important?

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Treating Chronic Pain with Opioids: Where are we?

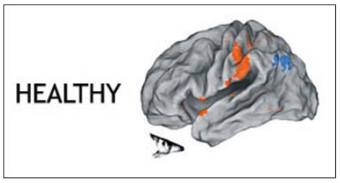
2016 AMCP Foundation 6th Annual Research Symposium
October 3, 2016

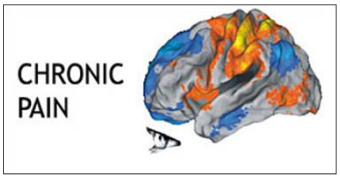
Peggy Compton, RN, PhD, FAAN
Georgetown University School of Nursing & Health Studies

Chronic Pain : a prevalent chronic disease

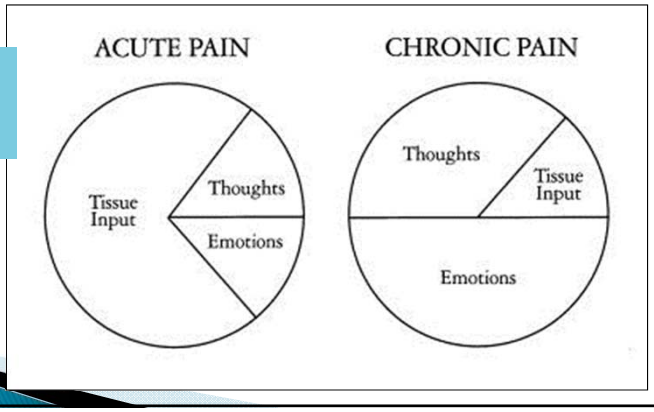
- Chronic pain impacts the daily lives of fully one-third of Americans over the age of 45
- Based on data from the 2012 National Health Interview Survey (NHIS), 25 million U.S. adults had daily chronic pain, and 23 million more reported severe pain.
- Prevalence will increase as population ages
- Estimated that between 5 and 8 million Americans use opioids on a daily basis from chronic pain management

Chronic pain "feels" different



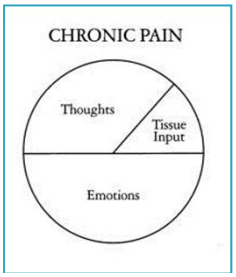


Sensory – tissue input
Affective – emotions
Cognitive – thoughts



Chronic Pain Management

- Analgesic medication is less important
- For tissue, focus on physical restoration
  - Exercise, physical therapy, stretching, yoga
  - Weight loss



- Manage affective and cognitive components of pain
  - cognitive-behavioral therapy
  - mindfulness-based therapy
  - acceptance and commitment therapy
- Functional outcomes are key
  - Quality of life – the ability to do what is important to the pt

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Provides recommendations on:

- when to initiate or continue opioids for chronic pain
- opioid selection, dosage, duration, follow-up and discontinuation
- ***assessing risk and addressing harms of opioid use***

Consensus across guidelines

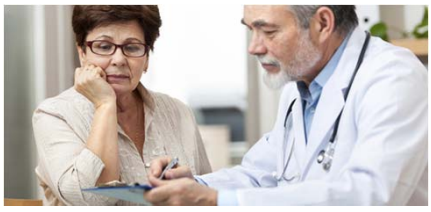
- Assessment
  - pain
  - Indication for opioid therapy
- Risk Stratification
  - approaches for selecting patients for opioid therapy
  - identify patients who are likely to have difficulty adhering to opioid therapy
  - those with a history of substance use disorder are at *high risk for poor treatment response*

Risk Assessment Tools

- SOAPP-R® (Screener and Opioid Assessment for Patients with Pain) (Butler et al., 2008)
  - 24 items, self-report
- ORT (Opioid Risk Tool) (Webster, 2005)
  - 5 items, self-Report
- BRI (Brief Risk Interview) (Jones et al., 2013)
  - 12 items, clinician administered

Consensus across guidelines

- Informed consent and mutually agreed upon treatment plan
  - Understand risks associated with opioid use
  - "trial" of opioid therapy
  - Include family
- Treatment agreement
  - Single primary provider
  - Refill policy
- Ongoing assessment
  - Pain and function
  - **Adherence monitoring**



Adherence monitoring
Risk for abuse, addiction, diversion

Low Risk	High risk
Random pill counts Random urine toxicology Prescription monitoring programs (PMPs) Use of monitoring tools	Increase visit frequency Shorter/smaller prescriptions Bring in addiction expertise

Monitoring Tools

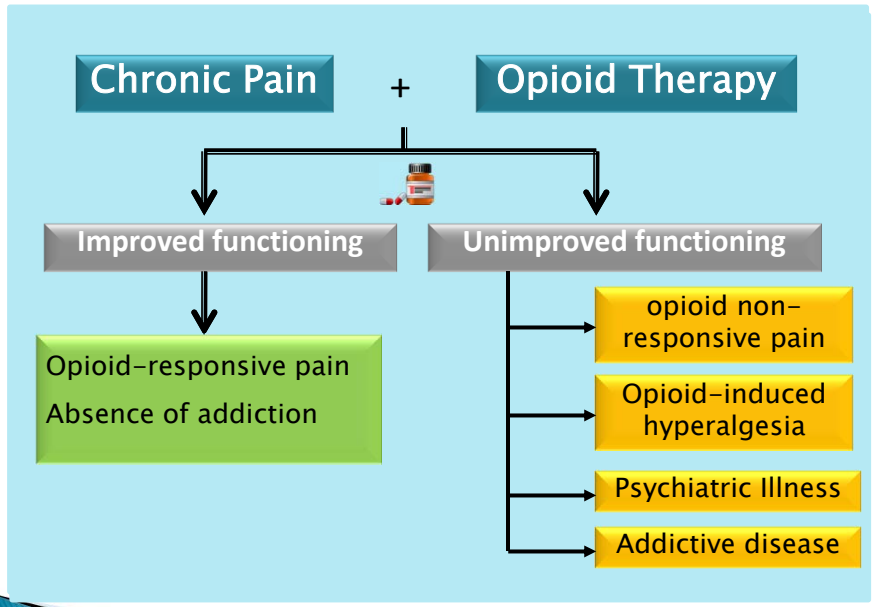
- COMM™ (Current Opioid Misuse Measure)
  (Butler et al, 2007)
- PDUQ (Prescription Drug Use Questionnaire) and self-report version PDUQ-p
  (Compton, et al., 1998; 2008)
- ABC (Addiction Behaviors Checklist)
  (Wu et al., 2006)
- PMQ (Pain Medicine Questionnaire)
  (Adams et al., 2004)
- POAC (Prescription Opioid Abuse Checklist)
  (Chabal et al., 1997)

Monitoring Tools

Composite Tools

- ABDI (Aberrant Drug Behavior Index) (Wasan et al, 2009)
  - high PDUQ score + positive UDT
- DMI (Drug Misuse Index)
  - High SOAPP score + High COMM score
  - High POTQ score + positive UDT (Wasan et al., 2007)
  - High PDUQ or High ABC score + positive UDT (Jamison et al., 2010)

* measure aberrant behaviors & behaviors in violation of treatment agreement, not substance use disorder



Adapted from: Weaver & Schnoll *The Clinical Journal of Pain* 2002 18:S61-S69
Mitra *Journal of Opioid Management* 2008 4:123-130.

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Recommendations: Assessing Risk and Addressing Harms of Opioid use

- Utilization of PMP q 1–3mo
- Urine drug testing at initiation of opioid therapy and at least annually
- Avoid prescribing opioid analgesics to those on benzodiazepines
- If opioid use disorder is present, refer to or arrange evidence-based treatment, perhaps including MAT

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Recommendations: Evaluate Risk factors for opioid-related harms

- Sleep discorded breathing, sleep apnea
- Pregnant women
- Renal or hepatic insufficiency
- Over 65 years of age
- Mental health conditions
- Substance use disorders
- Previous opioid overdose

Offer naloxone when present.

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Key Question 4 What is:

- "the accuracy of instruments for predicting risk for opioid overdose, addiction, abuse or misuse;
- the effectiveness of risk mitigation strategies;
- the effectiveness of risk management strategies;
- and comparative effectiveness of treatment strategies for managing patients with addiction"

Risk Mitigation Strategies

- Use of risk prediction instruments
- Use of opioid management/treatment agreement
- Patient education
- Urine toxicology
- Prescription Drug Monitoring Programs (PDMP)
- Monitoring tools or instruments
- Pill counts
- Use of abuse-deterrent formulations

REVIEW

Annals of Internal Medicine

The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop

Roger Chou, MD; Judith A. Turner, PhD; Emily B. Devine, PharmD, PhD, MBA; Ryan N. Hansen, PharmD, PhD; Sean D. Sullivan, PhD; Ian Blazina, MPH; Tracy Dana, MLS; Christina Bougatsos, MPH; and Richard A. Deyo, MD, MPH

Outcome	Studies	Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence
Risk assessment and risk mitigation strategies							
Diagnostic accuracy of instruments for predicting risk for opioid overdose, addiction, abuse, or misuse in patients with chronic pain being considered for long-term opioid therapy							
Opioid Risk Tool	3 studies of diagnostic accuracy (n = 496)	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
SOAPP, version 1	2 studies of diagnostic accuracy (n = 203)	High	Consistent	Direct	Imprecise	Undetected	Low
Effectiveness of risk prediction instruments on outcomes related to overdose, addiction, abuse, or misuse in patients with chronic pain							
Outcomes related to abuse	None	-	-	-	-	-	Insufficient
Effectiveness of risk mitigation strategies, including opioid management plans, patient education, urine drug screening, use of prescription drug monitoring program data, use of monitoring instruments, more frequent monitoring intervals, pill counts, and use of abuse-deterrent formulations, on outcomes related to overdose, addiction, abuse, or misuse							
Outcomes related to abuse	None	-	-	-	-	-	Insufficient
Comparative effectiveness of treatment strategies for managing patients with addiction to prescription opioids							
Outcomes related to abuse	None	-	-	-	-	-	Insufficient

Poor validity of Risk Assessment Tools:

- *GRADE 3* (observational studies)
- Sensitivity and specificity vary widely:
  - ORT – sens 0.58, 0.75; spec 0.54, 0.86
  - SOAPP-R – sens 0.53, 0.25; spec 0.62, 0.73
  - BRI – sens 0.73, 0.83; spec 0.43, 0.88
- Likelihood ratios essentially non-informative

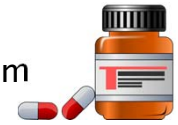
GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

- Emphasis on Responsible Prescribing
- Strong Recommendation for Opioid-sparing
- Community concern that will have a general chilling effect on opioid prescribing for chronic pain patients

Responsible opioid prescribing:

- Minimize opioids in community
- Minimize diversion
- Detect and address misuse and abuse
- Refer those with an opioid use disorder to treatment
- Increase focus on non-medication interventions
- SAVE LIVES

Opioid-sparing Strategies:



- Taper to lowest dose tolerable
- Increase vigilance ≥50 morphine milligram equivalents (MME)/day
- Avoid increasing dosage to ≥90 MME/day
  Limit length of prescription following acute pain
- Utilize non-opioid analgesics
  - NMDA antagonists
  - GABA agonists
  - Anti-inflammatory analgesics
  - Low dose opioid antagonists

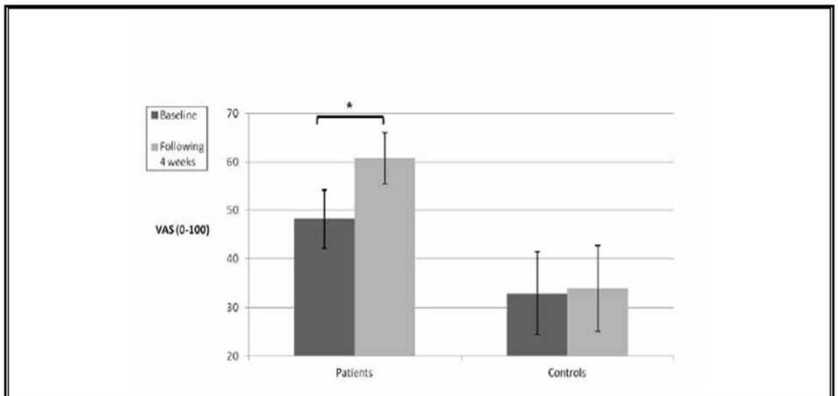
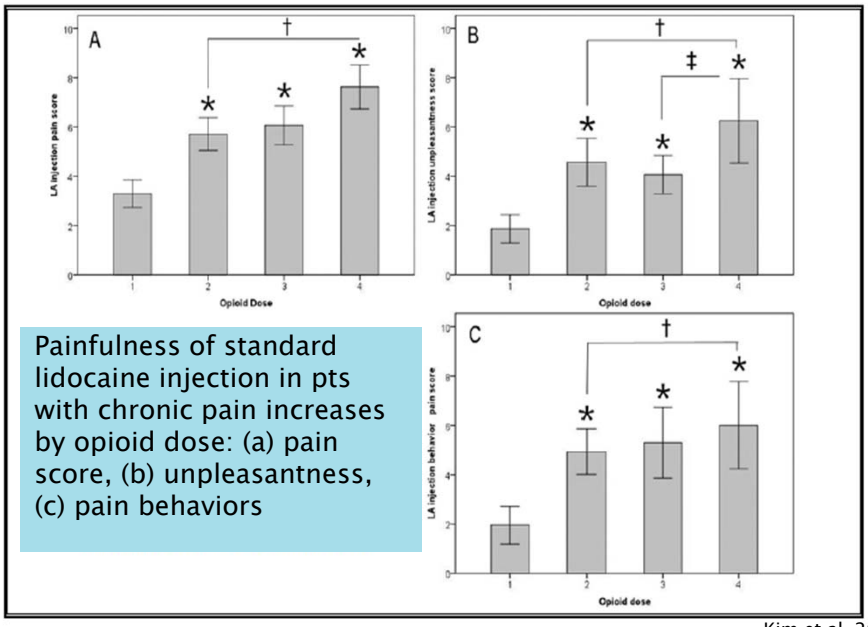


Fig. 3: *Intensity of the phasic heat pain response at baseline and following a 4-week regimen of oral hydromorphone treatment. Intensity of phasic heat pain response at baseline (dark grey) and 4 weeks later (light grey) (following 4 weeks of oral hydromorphone treatment for the patient group). A significant difference was found in the patient group ($P < 0.05$), but not in the control group. Data are presented as mean ± standard deviation.*

Heat pain more severe following 4wks hydromorphone treatment in patients with chronic pain

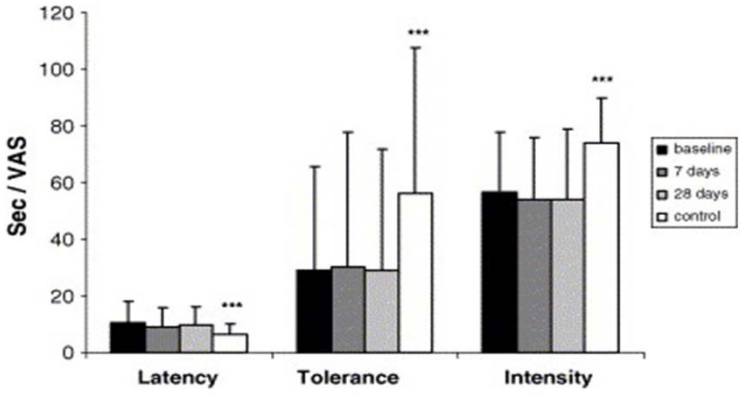
(Suzan et al., 2013)



Painfulness of standard lidocaine injection in pts with chronic pain increases by opioid dose: (a) pain score, (b) unpleasantness, (c) pain behaviors

Kim et al, 2013

Hyperalgesia persists 28 days following opioid detoxification

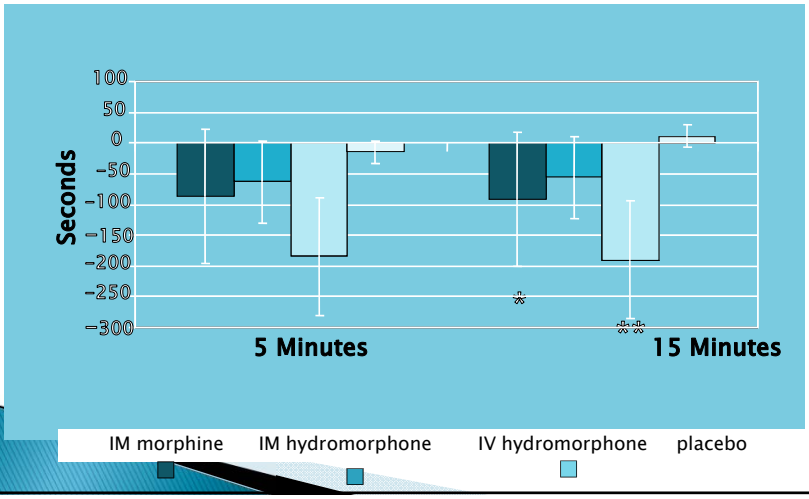


Pain responses of opioid addicts (OA) and controls across the study (means ± S.D.). Y-axis latency, tolerance, and pain intensity. ***p ≤ 0.0001 between controls and OAs. No differences between the three time points in the OAs group.

Pud et al., *Drug Alcohol Depend*. 2006 May 20;82(3):218-23.

Opioid taper

- "withdrawal hyperalgesia"
  - increased sensitivity to pain during opioid withdrawal



Treat Psychiatric Symptoms

- Rates of depression and anxiety disorders are high in chronic pain patients
- Chronic pain can worsen depression symptoms and is a risk factor for suicide in people who are depressed.
- Hypothesized association between chronic pain, *central pain amplification*, and psychological distress.

http://www.nimh.nih.gov/health/publications/depression-and-chronic-pain/index.shtml

Interventions for Chronic disease management

- Motivational interviewing
- Cognitive behavior therapy
- Psychiatric assessment
- Stress management
- Functional Assessment

Thank you!

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