Balancing Access and Use of Opioid Therapy
Challenges Confronting Health Plans, Payers, Prescribers and Others

Welcome
Paula J. Eichenbrenner, CAE
AMCP Foundation Executive Director
Welcome

Brett Norman
Symposium Moderator
POLITICO Health Policy Editor

Overview on Opioid Pain Therapy Misuse and Abuse and Federal Initiatives

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U.S. Department of Health and Human Services (HHS)
The Opioid Epidemic and the Federal Response

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Director, Division of Science Policy
Office of the Assistant Secretary for Planning and Evaluation

Overview

- Epidemiological trends
- HHS Opioid Initiative
- Conclusions
Past year nonmedical use of prescription opioids and heroin use

Past year opioid use disorders, US, 2003-2014

Source: SAMHSA, NSDUH 2002-2014 PUF
Opioid-related overdose deaths, US, 1999-2014

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

**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

**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

**aHR for heroin transition**

- PO dependence (lifetime): 2.4
- Early initiation (≤ 15 years): 3.1
- Only use PO to get high (lifetime): 4.8
- Non-oral route most often: 6.6

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

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

[Graph showing the correlation between the rate of heroin-related overdose deaths and the rate of past year heroin abuse or dependence from 2002 to 2013.]


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

Synthetic opioid deaths closely linked to fentanyl submissions

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
IMPROVING OPIOID PRESCRIBING

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

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

Some states have more painkiller prescriptions per person than others.

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, SAMSHA
- 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

People with opioid use disorders are not receiving treatment

Source: Jones CM 2016 NSDUH PUF

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Individuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Opioid Use Disorder</td>
<td>2,239,768</td>
</tr>
<tr>
<td>Received Treatment for Illicit Drugs or Alcohol Use in Past Year</td>
<td>655,575</td>
</tr>
<tr>
<td>Received Treatment at Specialty Facility</td>
<td>520,972</td>
</tr>
</tbody>
</table>

Source: Jones CM 2016 NSDUH PUF
## Reasons why people didn’t get treatment

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Cost/No Insurance/Insurance didn’t cover treatment</td>
<td>47.8</td>
</tr>
<tr>
<td>Not ready to stop use/Didn’t feel need for treatment/Could handle problem without treatment</td>
<td>35.0</td>
</tr>
<tr>
<td>Stigma</td>
<td>30.2</td>
</tr>
<tr>
<td>Awareness of treatment</td>
<td>12.3</td>
</tr>
<tr>
<td>Other</td>
<td>11.7</td>
</tr>
<tr>
<td>Availability of treatment</td>
<td>10.2</td>
</tr>
</tbody>
</table>

Source: Jones CM 2016 NSDUH PUF

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

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


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

PRESIDENT OBAMA’S BUDGET WILL INVEST $1.1 BILLION TO HELP ADDRESS THE OPIOID EPIDEMIC

$920 million will expand access to medication-assisted treatment, increase capacity and make services more affordable for Americans in all 50 states →
INCREASING USE OF NALOXONE

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

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

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

Pharmacy dispensing of naloxone in the US, 2010-2015

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
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.)

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.
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

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.
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.

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.
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.

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.
ATAG Recommendations

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

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
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.

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.
AMCP Advocacy on CARA

Task Force on Pain Management

Improve Access to Overdose Treatment

NASPER Reauthorization

Medication-assisted Treatment for Recovery
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.
The Path of Pain: Maze or Labyrinth?

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and  
SageLife, LLC

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Glenna@sagemylife.com  
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Know the difference?

Maze  
Labyrinth
Garden Labyrinth

My Path of Pain
The Labyrinth Metaphor

Hidden Spiral Labyrinth
Overview

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

Surgeries Timeline

Birth 10 20 30 40 50 60 70

Surgeries
Injuries Timeline

<table>
<thead>
<tr>
<th>Birth</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>60</th>
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<td>•</td>
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<td></td>
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<tr>
<td>Injuries</td>
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<td>•</td>
<td>•</td>
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</table>

Chronic Pain-Related Timeline

<table>
<thead>
<tr>
<th>Birth</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
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<td>Surgeries</td>
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<td>•</td>
<td>•</td>
<td>•</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injuries</td>
<td>•</td>
<td>•</td>
<td>•</td>
<td></td>
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</tr>
<tr>
<td>Chronic</td>
<td>Osgood-Schlatter’s</td>
<td>Post-trauma TMJ</td>
<td>Endometriosis</td>
<td>Post-trauma Hit-and Run</td>
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<td></td>
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</tbody>
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### Condition-Related Timeline

#### Birth 10 20 30 40 50 60 70

**Surgeries**
- [ ]
- [ ]
- [ ]
- [ ]
- [ ]

**Injuries**
- [ ]
- [ ]
- [ ]

**Chronic**
- [ ] Osgood-Schlatter’s
- [ ] Endometriosis
- [ ] Post-trauma TMJ
- [ ] Post-trauma Hit-and-Run

**Condition**
- [ ] Scoliosis

### Summary Timeline

#### Birth 10 20 30 40 50 60 70

**Surgeries**
- [ ]
- [ ]
- [ ]
- [ ]
- [ ]

**Injuries**
- [ ]
- [ ]
- [ ]

**Chronic**
- [ ] Osgood-Schlatter’s
- [ ] Endometriosis
- [ ] Post-trauma TMJ
- [ ] Post-trauma Hit-and-Run

**Condition**
- [ ] Scoliosis
### “In Your Face” Impact

<table>
<thead>
<tr>
<th>Grief, Loss, Longing</th>
<th>Other</th>
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<tbody>
<tr>
<td>• Normalcy</td>
<td>• Fear</td>
</tr>
<tr>
<td>• Wholeness</td>
<td>• Vulnerability</td>
</tr>
<tr>
<td>• Relaxation</td>
<td>• Helplessness</td>
</tr>
<tr>
<td>• Safety</td>
<td>• Shame</td>
</tr>
<tr>
<td>• Confidence in the body</td>
<td>• Alienation from self/others</td>
</tr>
<tr>
<td>• Trust in others</td>
<td>• Rejection/social isolation</td>
</tr>
<tr>
<td>• Idealization of others</td>
<td>• Anger-Depression Loop</td>
</tr>
<tr>
<td>• Authenticity</td>
<td>• Constriction</td>
</tr>
<tr>
<td>• Life meaning</td>
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### Early Pain Management

<table>
<thead>
<tr>
<th>Professionals</th>
<th>Products</th>
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<tbody>
<tr>
<td>• Physicians</td>
<td>• Tylenol with Codeine #3,</td>
</tr>
<tr>
<td></td>
<td>1-2 days post-op</td>
</tr>
<tr>
<td>• Surgeons</td>
<td>• OTC Pain Relievers</td>
</tr>
<tr>
<td>• Dentists</td>
<td></td>
</tr>
</tbody>
</table>
### Later Pain Management

<table>
<thead>
<tr>
<th>Professionals</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td>Motrin + Valium, one dose in TMJ clinical trial</td>
</tr>
<tr>
<td>Clinical Researchers</td>
<td>OTC Pain Relievers</td>
</tr>
<tr>
<td></td>
<td>Metaxalone</td>
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<tr>
<td></td>
<td>Modafanil</td>
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### Canyon Ranch Alternative “Finds”

<table>
<thead>
<tr>
<th>Acupuncture</th>
<th>Reiki</th>
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<tbody>
<tr>
<td>Strength training</td>
<td>Hypnotherapy</td>
</tr>
<tr>
<td>Eye Movement</td>
<td>Massage Therapists</td>
</tr>
<tr>
<td>Desensitization &amp;</td>
<td>Neuromuscular Massage Therapists</td>
</tr>
<tr>
<td>Reprocessing</td>
<td>Mindfulness Meditation</td>
</tr>
<tr>
<td>Emotional Freedom</td>
<td>Nutrition, Wellness and Sleep</td>
</tr>
<tr>
<td>Technique (Tapping)</td>
<td></td>
</tr>
<tr>
<td>Healing Touch</td>
<td></td>
</tr>
</tbody>
</table>
Other Alternative “Finds”

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

No-Longer a Hidden Metaphor
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

Prescription Drug Monitoring Programs (PDMPs)

Patient Review and Restriction Programs (PRRs)
91 percent of patients with a nonfatal overdose continue to receive opioids

But there’s more to the story…
Multiple Provider Episodes Increase the Risk of Patient Harm

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
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

PRR characteristics and structures can:
- Impact effectiveness
- Support or inhibit improved patient care

Example Criteria Used by Medicaid PRRs for Patient Enrollment
- Number of pharmacies
- Number of prescribers
- Number of controlled substance prescriptions
- Evidence of therapeutic duplication
Most States Use Multiple Criteria to Identify At-Risk Patients

Over 50% of Medicaid PRR programs are not offering patients additional services to improve patient care.
Access to PDMPs May Improve Effectiveness of PRRs

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
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
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.
- Manufacturers and FDA consider development of abuse-deterrent formulations a priority and are aggressively encouraging their development.

Segal J. 2013.
• 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
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.
PCSS Projects

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

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.
Substance Use Disorder Facts

- 20% of drug-related hospital admissions are due to heroin and opiates*

- In 2015, deaths from opioid/heroin overdoses overtook deaths from automobile accidents*

*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

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

² Past Year Use
³ Monitoring the Future Survey, 2011
⁴ National Survey on Drug Use and Health, 2010

Abuse of Prescription (Rx) Drugs Affects Young Adults Most

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

² Monitoring the Future Survey, 2011
³ National Survey on Drug Use and Health, 2010
Abuse of Prescription (Rx) Drugs Affects Young Adults Most

CONSEQUENCES

More than 1.700 young adults, ages 18-24, died from Rx drug overdose in 2014—a 4-fold increase since 1999.

Among young adults, for every death due to Rx drug overdose, there were:

119 Emergency Room Visits

& 22 Treatment Admissions

...nearly 5 persons per day


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.
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.

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
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

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

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

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 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.

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.
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.

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.
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.

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
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.

Since 1999, sales of prescription opioids in the U.S. have quadrupled.

Image from CDC: http://www.cdc.gov/drugoverdose/index.html
Image from CDC: http://www.cdc.gov/drugoverdose/data/prescribing.html

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 Guidelines 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 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 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 a 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 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 of 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
NABP: Update on Prescription Monitoring Programs

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

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.
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.
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
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.

Main shortcoming of PMPs: Patients cross state borders

Solution – PMP InterConnect
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

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.
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.

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
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.

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.
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

• 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

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
**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
OEND programs as of June 2014

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)
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)

Naloxone Prescribing & Dispensing Rates Are Growing But Remain Low

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

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

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

Source: SFDPH naloxone detailing provider’s guide
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

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
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

Questions
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
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
- 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

**Methods**
- Measures
  - ERO and IRO
  - Duration of use
  - Dose change

---

Patients Receiving Opioids

98M patients
In the Truven database

18.34M patients received an opioid

ERO=extended-release opioid, IRO=immediate release opioid.
Incident ERO Patients

98M patients in the Truven database

- 70,934 Incident ERO
  - 35,754 Single script
  - 15,376 Single episode
  - 12,812 Multi-episode
  - 6,992 Continuous users

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

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

98M patients in the Truven database

- 6,992 Continuous users

- 5,019 (72%) 2 EROs
- 1,453 (21%) 2 EROs
- 120 (2%) 4+ EROs
- 400 (6%) 3 EROs

- 120 (2%) 1 ERO
Defining Dose Changes: Titration and Excursion

**Titration**

- **Up titration**
  - Opioid Dose (morphine equivalents)
  - Days
  - >60 days
  - 80 mg
  - 40 mg
  - 20 mg
  - 0 mg

- **Down titration**
  - Opioid Dose (morphine equivalents)
  - Days
  - >60 days

**Excursion**

- **Up excursion**
  - Opioid Dose (morphine equivalents)
  - Days
  - ≥60 days
  - Return to previous dose

- **Down excursion**
  - Opioid Dose (morphine equivalents)
  - Days
  - ≤60 days
  - Return to previous dose

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

- 3,465 Continuous, 1 ERO, Multiple doses
  - 3,064 (90%) Multiple doses
  - 391 (11%) 1 dose

- 98M patients
  - in the Truven database

- 5,019 Continuous users: 1 ERO
  - 3,465 Continuous, 1 ERO, Multiple doses
  - 311 Excursion Only
  - 864 Titration+ Excursion
  - 2,290 Titration Only

- 926 (27%) Mixed
- 1,328 (58%) Up only
- 63 (7%) Down only

- 930 1 up titration
- 545 Mixed
- 256 Up only
- 63 Down only

- Titration+ Excursion Only
- 864

- Titration Only
- 2,290

- Excursion Only
- 311

- AMCP Foundation 2016 Research Symposium Presentations Page 84 of 118
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 criteria:
  - 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

Excess Health Care Costs

<table>
<thead>
<tr>
<th>Month</th>
<th>Baseline</th>
<th>6 months before first abuse diagnosis</th>
<th>6 months after first abuse diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Abusers</td>
<td>Non-abusers</td>
<td>Abusers</td>
</tr>
<tr>
<td>-12</td>
<td>$2</td>
<td>$56</td>
<td>$2</td>
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<td>-11</td>
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<tr>
<td>6</td>
<td>$5,000</td>
<td>$6,000</td>
<td>$5,000</td>
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</table>

First abuse diagnosis
### Excess Costs Before Diagnosis

<table>
<thead>
<tr>
<th>Total Health Care Costs</th>
<th>$11,726</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient costs (total)</td>
<td>$729</td>
</tr>
<tr>
<td>Alcohol dependence syndrome</td>
<td>$69</td>
</tr>
<tr>
<td>Other diseases of lung</td>
<td>$62</td>
</tr>
<tr>
<td>Drug dependence (excluding opioids)</td>
<td>$67</td>
</tr>
<tr>
<td>Emergency department costs (total)</td>
<td>$1,431</td>
</tr>
<tr>
<td>Other symptoms involving abdomen and pelvis</td>
<td>$68</td>
</tr>
<tr>
<td>General symptoms</td>
<td>$52</td>
</tr>
<tr>
<td>Diseases of pancreas</td>
<td>$46</td>
</tr>
<tr>
<td>Rehabilitation facility costs (total)</td>
<td>$274</td>
</tr>
<tr>
<td>Drug dependence (excluding opioids)</td>
<td>$152</td>
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<tr>
<td>Alcohol dependence syndrome</td>
<td>$102</td>
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<tr>
<td>Episodic mood disorders</td>
<td>$11</td>
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<td>Outpatient/other costs (total)</td>
<td>$584</td>
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<tr>
<td>Drug dependence (excluding opioids)</td>
<td>$183</td>
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<tr>
<td>Alcohol dependence syndrome</td>
<td>$123</td>
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<tr>
<td>Other and unspecified disorders of back</td>
<td>$75</td>
</tr>
<tr>
<td>Prescription drug costs</td>
<td>$66</td>
</tr>
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</table>

### Excess Costs After Diagnosis

<table>
<thead>
<tr>
<th>Total Health Care Costs</th>
<th>$11,726</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient costs (total)</td>
<td>$2,880</td>
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<tr>
<td>Drug dependence (opioids)</td>
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<td>Drug dependence (excluding opioids)</td>
<td>$242</td>
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<tr>
<td>Alcohol dependence syndrome</td>
<td>$173</td>
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<tr>
<td>Emergency department costs (total)</td>
<td>$2,306</td>
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<tr>
<td>Poisoning by analgesics (opioids)</td>
<td>$189</td>
</tr>
<tr>
<td>Drug dependence (opioids)</td>
<td>$135</td>
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<tr>
<td>Other diseases of lung</td>
<td>$125</td>
</tr>
<tr>
<td>Rehabilitation facility costs (total)</td>
<td>$2,324</td>
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<tr>
<td>Drug dependence (opioids)</td>
<td>$1,077</td>
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<tr>
<td>Drug dependence (excluding opioids)</td>
<td>$607</td>
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<tr>
<td>Alcohol dependence syndrome</td>
<td>$339</td>
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<td>Outpatient/other costs (total)</td>
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<td>Drug dependence (opioids)</td>
<td>$1,487</td>
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<tr>
<td>Drug dependence (excluding opioids)</td>
<td>$1,026</td>
</tr>
<tr>
<td>Alcohol dependence syndrome</td>
<td>$398</td>
</tr>
<tr>
<td>Prescription drug costs</td>
<td>$310</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Device</th>
<th>Simple Movement</th>
<th>Multi-channel Movement</th>
<th>Sensing Options</th>
<th>Feedback Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wristband</td>
<td></td>
<td></td>
<td>Heartrate, GPS Self-report</td>
<td></td>
</tr>
<tr>
<td>Patch</td>
<td></td>
<td>Multi-channel</td>
<td>Sweat, Sweat chemistry, Blood</td>
<td>Blood chemistry</td>
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<tr>
<td>Lens</td>
<td></td>
<td></td>
<td>Tear chemistry</td>
<td></td>
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<tr>
<td>Implant</td>
<td></td>
<td>Multi-channel</td>
<td>Blood chemistry</td>
<td></td>
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<tr>
<td>Bottle Cap</td>
<td></td>
<td>Simple</td>
<td>Drug adherence</td>
<td></td>
</tr>
<tr>
<td>Pill Cam/Sensor</td>
<td></td>
<td>Simple</td>
<td>GI Chemistry, GI visual</td>
<td></td>
</tr>
</tbody>
</table>

Require intermediary device for data upload
This is not the Future, it is Now

$85-$250

$190-$1050

$200-$650

$30

$500

Overarching concept
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

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
Total Opioid Management

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

Opioid abuse: A national epidemic and public health emergency

- **4.5 Million Addicts**
- **44 Daily Deaths**
- **14%** Record increase in opiate-related deaths in U.S. from 2013 – 2014
- **$56 Billion** Annual U.S. Societal Costs of Rx opiate abuse

Disheartening statistics

- 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

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
Why Optum is uniquely positioned to lead in this area

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)
- Actively promoting routine Prescription Drug Monitoring Program adoption/use

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

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
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

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
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

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

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
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

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
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).

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
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

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

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.

**Comparative effectiveness**
Compared 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
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?

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?
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 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

<table>
<thead>
<tr>
<th>Low Risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>› Random pill counts</td>
<td>› Increase visit frequency</td>
</tr>
<tr>
<td>› Random urine toxicology</td>
<td>› Shorter/smaller prescriptions</td>
</tr>
<tr>
<td>› Prescription monitoring programs (PMPs)</td>
<td>› Bring in addiction expertise</td>
</tr>
<tr>
<td>› Use of monitoring tools</td>
<td></td>
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</tbody>
</table>

### 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

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**Chronic Pain + Opioid Therapy**

- **Improved functioning**
  - Opioid-responsive pain
  - Absence of addiction
- **Unimproved functioning**
  - Opioid non-responsive pain
  - Opioid-induced hyperalgesia
  - Psychiatric Illness
  - Addictive disease

Adapted from: Weaver & Schnoll *The Clinical Journal of Pain* 2002 18:S61–S69
GUIDEINE 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

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
• **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.

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

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

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.

Interventions for Chronic disease management

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

Thank you!

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