Preventing Opioid Misuse in the Management of Pain Workshop

March 7, 2016

Washington, DC

pcori®

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Housekeeping

Today's webinar is open to the public and is being recorded.

- Members of the public are invited to listen to this webinar.
- Topic briefs and other materials are available on the PCORI site.
- Comments may be submitted via chat. No public comment period is scheduled today.

Reminders for the group

- Please signify your intent to speak by standing your name placard on end.
- Where possible, we encourage you to avoid acronyms in your discussion of these topics.

For those on the phone

- If you experience any technical difficulties, please alert us via chat or email support@meetingbridge.com.

Reminders

- Adhere to the schedule.
- Silent mobile devices.
- Mute your mic when not speaking.
- Disagree with ideas, not people.
- Be mindful of time constraints during the discussion.

Agenda

Agenda Item	Presenter/Facilitator	Time
Discussion of Research Gaps	Linda Porter, PhD Penny Mohr, MA	9:45 – 10:15 AM
Breakout sessions- Critical Gaps in Evidence	David Gastfriend, MD Erin Krebs, MD, MPH Doris Lotz, MD, MPH Caleb Alexander, MD	10:30 AM – 12:30 PM
Report Back and Discussion: Priority Research Questions for PCORI and Justification	Linda Porter, PhD	1:00 – 2:15 PM
Voting	Andrea Brandau, MPP	2:15 – 2:30 PM
Outcome of Vote and Discussion	Penny Mohr, MA	2:45 – 3:45 PM
Closing Remarks	Steve Clauser, PhD, MPA	3:45 – 4:00 PM

Why this is an important question and PCORI's initiative set in the context of other Federal initiatives

Linda Porter, PhD
Director, Office of Pain Policy
National Institute on Neurological Disorders and Stroke (NIH/NINDS)

PCORI: Strike a Balance

"Pain- It has no future but itself"

Emily Dickinson

100 million
23 million
635 billion

198 million
2 million
28,000

"Improving the way opioids are prescribed ..... can ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these powerful drugs".

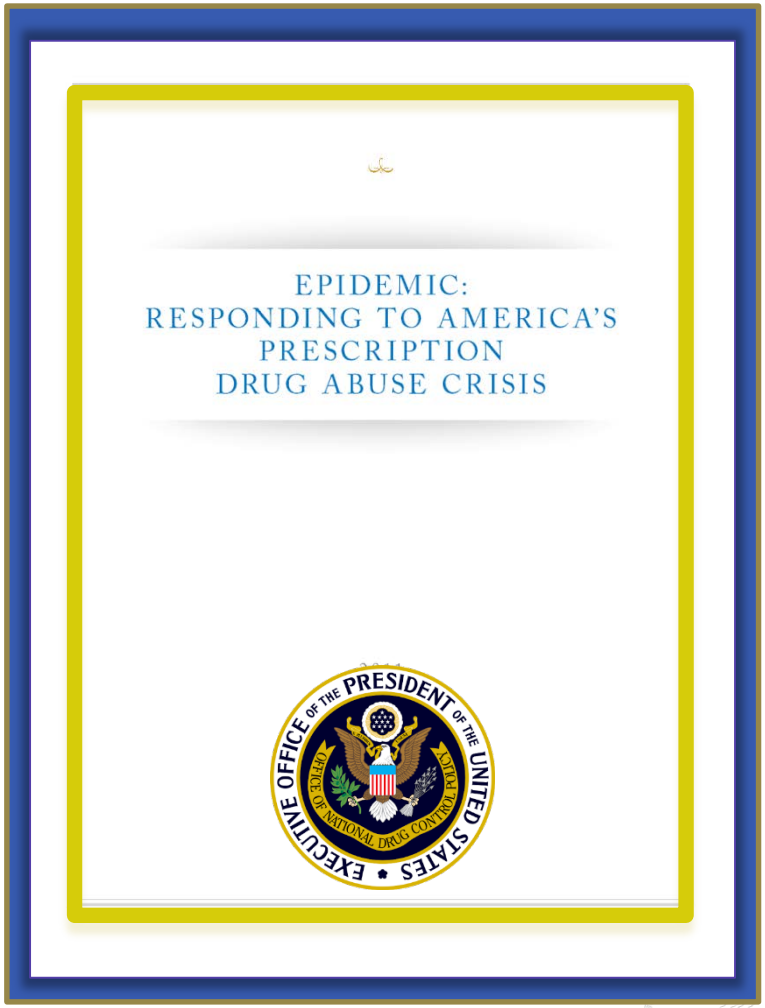
"The potent medications science has developed have great potential for relieving suffering, as well as great potential for abuse".

"Any policy 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".

The Whitehouse
ONDCP National Drug Abuse Action Plan

Reduce prescription drug abuse and other harm from drugs

- Education
- Monitoring
- Proper medication disposal
- Enforcement



The President's Budget

$ 1 billion to expand access to treatment for prescription drug abuse and heroin use

- Support states to expand access to medication-assisted treatment for opioid use disorder
- Expand access to substance abuse treatment providers

~ $500 million to expand state-level prescription drug overdose prevention strategies

- Improve access to naloxone
- Improve treatment access in rural areas

NIH
National Institutes of Health

DHHS Secretary's Initiative

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

- Improving opioid prescribing practices to reduce opioid disorder and overdose
- Expanding use and distribution of naloxone to treat opioid overdoses
- Expanding medication-assisted treatment to reduce opioid use disorders and overdose

Office of the Assistant Secretary: ODPHP

http://health.gov/hcq/training.asp#pathways

OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION

U.S. PUBLIC HEALTH

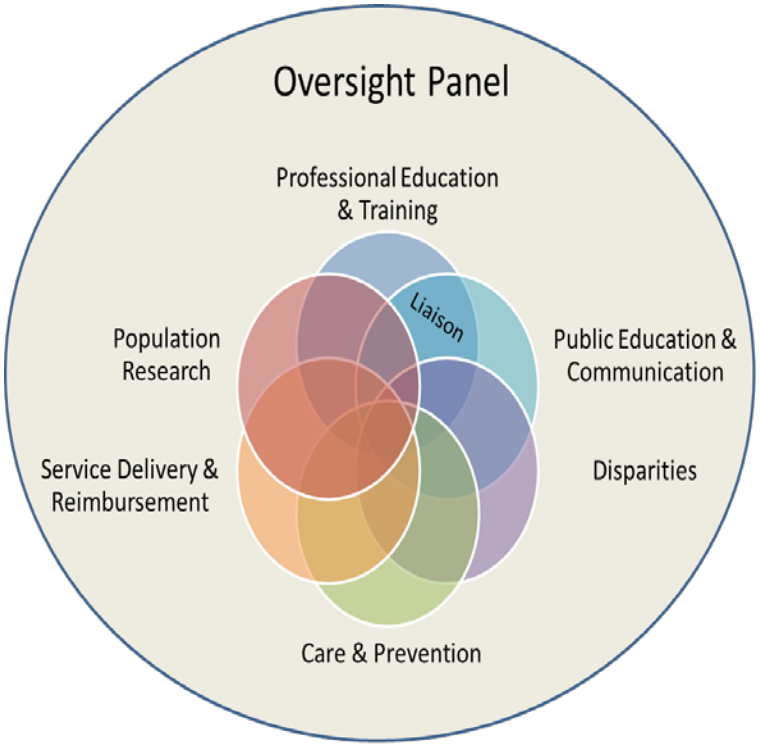
DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Trans-Agency Initiative

A Comprehensive Population Health Level Strategy for Pain

National Pain Strategy

- IOM: "develop a comprehensive, population health-level strategy for pain prevention, treatment, management, education, reimbursement, and **research** that includes specific goals, actions, time frames, and resources."



National Institutes of Health

Federal Pain Research Strategy

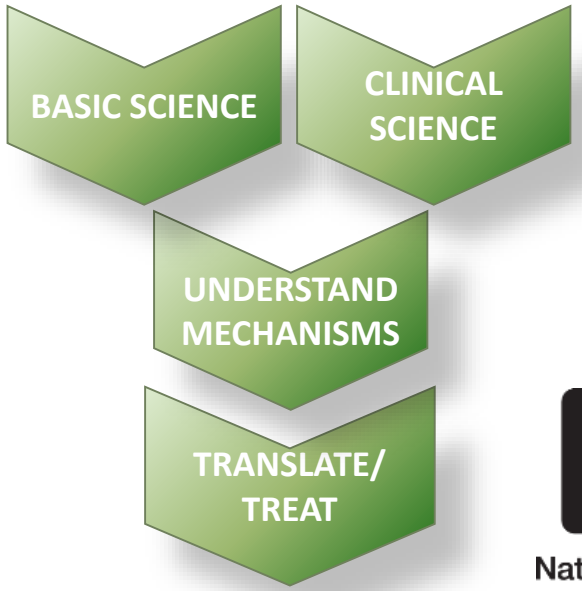
The CONTINUUM of PAIN: the characterization of pain as a temporal process, beginning with an acute stage, which may progress to a chronic state of variable duration. Chronic pain may start early after injury or surgery, because of an individual's susceptibility, through mechanisms activated in the acute setting.

- PREVENTION OF ACUTE & CHRONIC PAIN
- ACUTE PAIN & ACUTE PAIN MANAGEMENT
- TRANSITION FROM ACUTE TO CHRONIC PAIN
- CHRONIC PAIN & CHRONIC PAIN MANAGEMENT
- DISPARITIES

WHAT HAPPENS AND TO WHOM?

WHY AND HOW DOES IT HAPPEN?

HOW TO MANAGE?



NIH
National Institutes of Health

CDC Guideline for Prescribing Opioids for Chronic Pain

- ✓ **Primary care providers, outpatient settings, adults**
  - Determining 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
- ❑ Non-opioid therapy is preferred for chronic pain
- ❑ The lowest possible effective dosage should be prescribed to reduce risks of opioid use disorder and overdose.
- ❑ Providers should exercise caution when prescribing opioids and monitor all patients closely.

The FDA Action Plan

- Expand use of advisory committees
- Develop warnings and safety information for immediate-release opioid labeling
- Strengthen post-market requirements to collect data
- Update Risk Evaluation and Mitigation Strategy (REMS) Program
- Expand access to abuse-deterrent formulations (ADFs) to discourage abuse
- Support better treatment
- Reassess the risk-benefit approval framework for opioid use

Research Recommendations

- Identify the types of pain, diseases, and patients most likely to benefit and incur harm from opioids.
- Develop and evaluate multidisciplinary pain interventions, cost-benefit analyses, and identify barriers to access.
- Develop and validate research measurement tools for identification of risk and outcomes related to long-term opioid use, which can be adapted for clinical settings.
- Develop alternative designs to randomized clinical trials on the effectiveness and harm of opioids
- Develop risk identification and mitigation strategies for clinical care and to assess how policy initiatives impact patient/public health outcomes.
- Facilitate evidence-based decision-making at every step of the clinical decision process.

PCORI's Interest in Pain Management and Opioid Research and Goals for the Day

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

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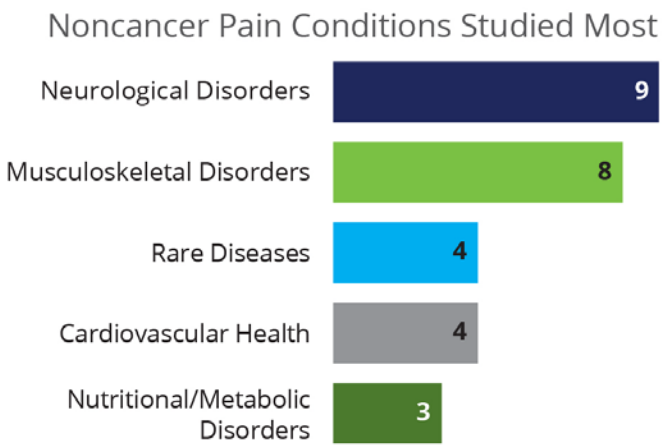
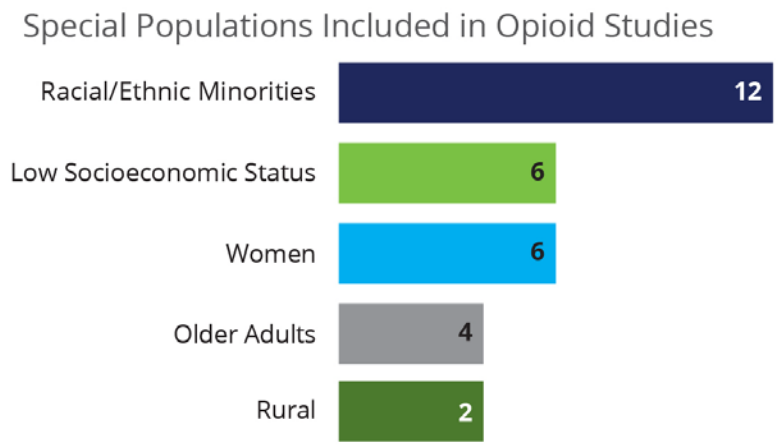
PCORI's Portfolio in Chronic Pain

As of December 2015, PCORI has funded **42** CER projects on noncancer chronic pain management or opioid use.





PCORI's Portfolio in Opioid-Related Studies

- **13** studies that focus on opioids or have outcome measures related to opioid use or harms
  - 11 in chronic pain
  - 2 address both chronic and acute pain
- Most address improved chronic pain management with opioid use as one of the outcomes (not primary)
- A few focus on strategies aimed to reduce opioid use or dose, including:
  - Prescription Opioid Management in Chronic Pain Patients: A Patient-Centered Activation Intervention (Campbell)
  - Evaluation of a health plan initiative to mitigate chronic opioid therapy risks (Von Korff)
  - Optimizing Patient Engagement in a Novel pain management initiative (OPEN) (Green)
- 3 studies specifically look at opioid-related harms

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

- **Advisory workshop on June 9, 2015**
  - » Identification of priority questions and refinement
- **Targeted Funding Announcement – October 2015**
  - » 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?
  - » $40 million for up to 4 awards
- **Awards anticipated July 2016**

Focus of this Workshop

What is the comparative effectiveness of alternative strategies for decreasing the **inappropriate** initiation of opioids for managing noncancer pain in primary care while improving patient outcomes (e.g., functioning, quality of life, reducing pain) and reducing patient harms (e.g., opioid misuse, abuse, overdose)?

Focus of this Workshop

What is the comparative effectiveness of alternative strategies for **decreasing the inappropriate initiation of opioids** for managing noncancer pain in primary care while **improving patient outcomes** (e.g., functioning, quality of life, reducing pain) and reducing patient harms (e.g., opioid misuse, abuse, overdose)?

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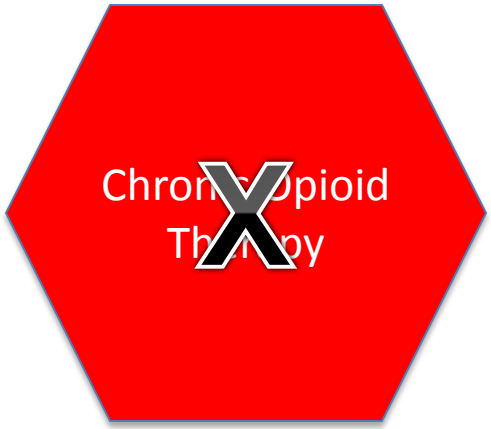

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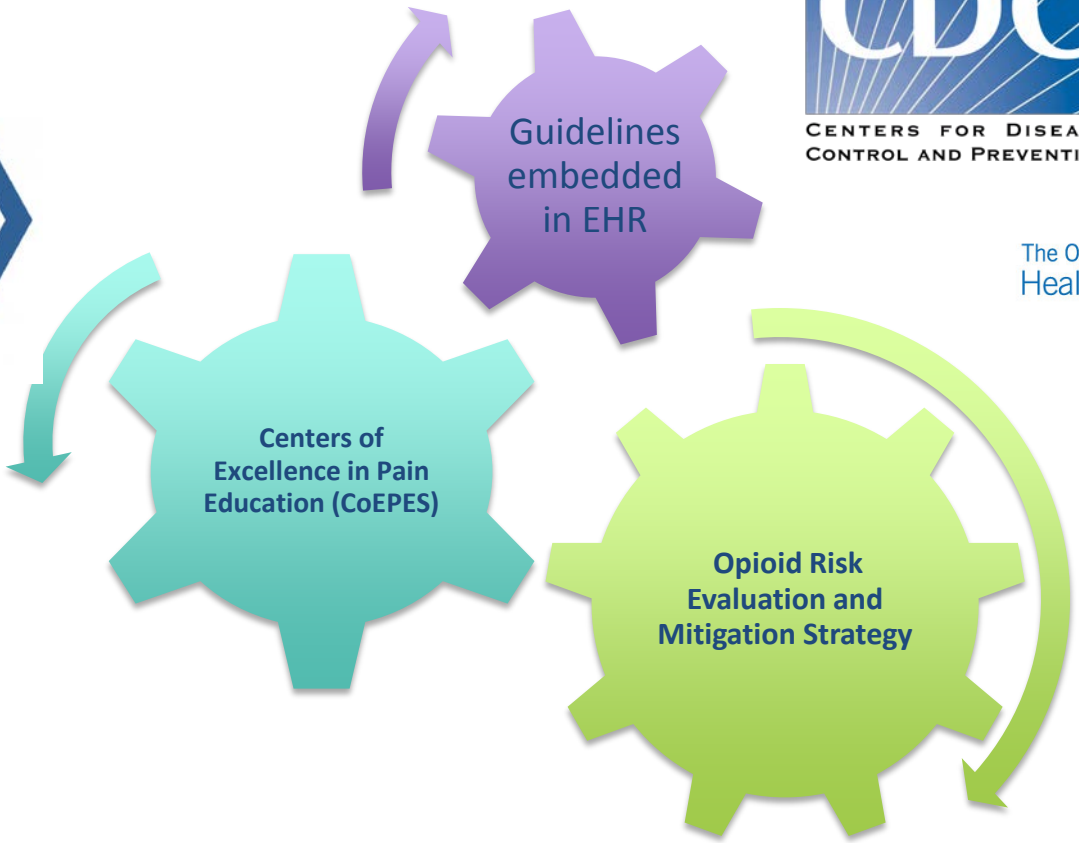
Strategies to Reduce Misuse and Inappropriate Prescribing for Acute versus Chronic Pain

Acute Pain — **Chronic Pain**

Major issue is number of tablets, duration of treatment

Major issues are:
limited access to alternative interventions, such as cognitive behavioral therapy or physical therapy;
Providers lack training in recommended multimodal approach; patient education is time consuming

Example of Physician/Patient Communication and Dissemination Strategy: Leveraging Federal Initiatives for PCOR



NIH

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

The Office of the National Coordinator for Health Information Technology

FDA
U.S Food and Drug Administration

Example of Comprehensive Health Systems Strategy: Kaiser Permanente

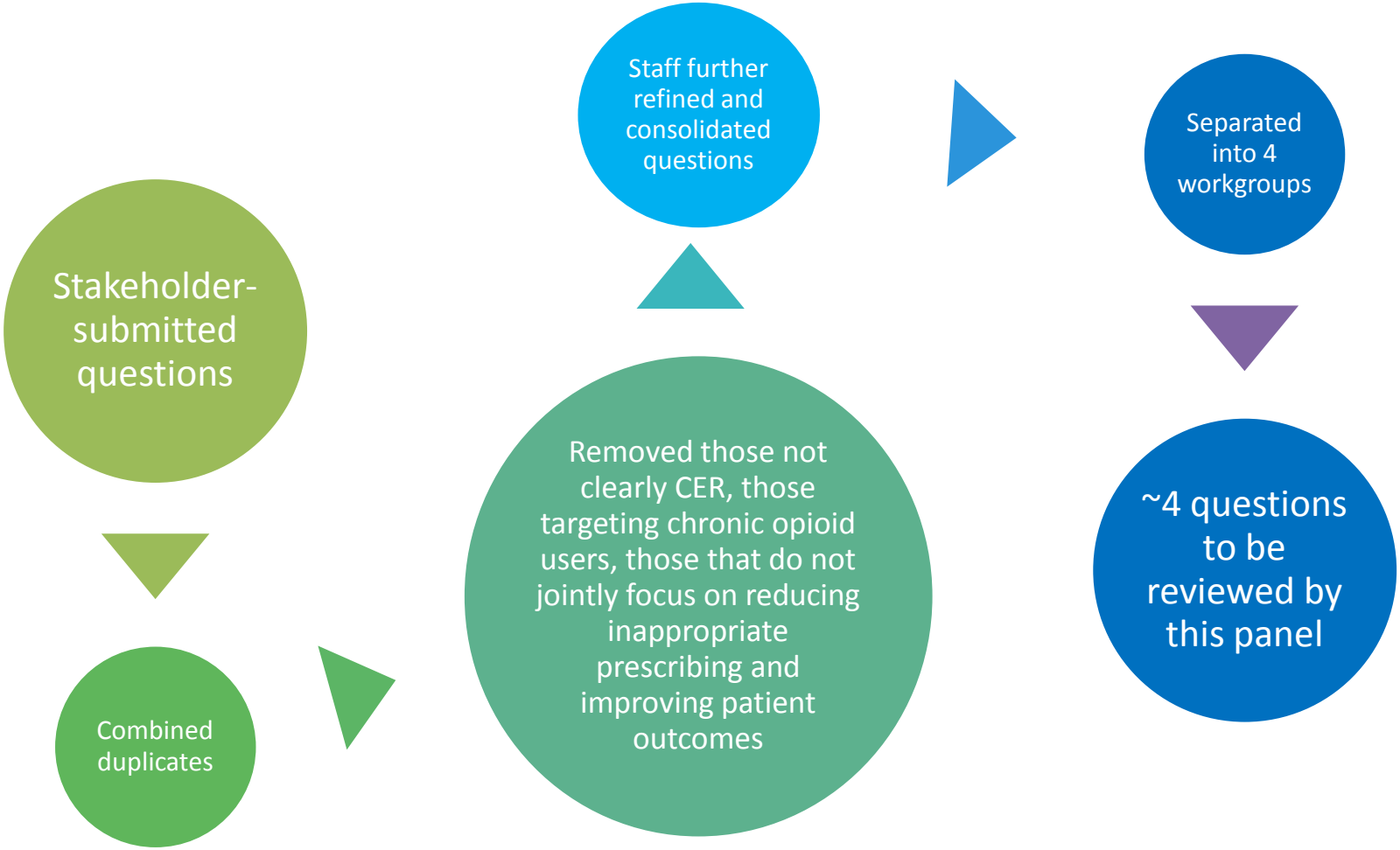
- » Developed evidence-based guidelines
- » Prescriber education and training
- » Patient education
- » Population health management
- » Expanded role of the pharmacist
- » Access to substance use treatment

- **Opioid use declined 72% between 2010 and 2013**
- **What about patient outcomes?**

Example of Payer Strategy: Medicaid-Oregon Health Plan

- January 2016 expansion of benefits for alternatives to opioids for back pain patients
  - Allows up to 30 visits per year to providers offering nonpharmacologic alternatives such as:
    - » Acupuncture
    - » Chiropractic
    - » Cognitive behavioral therapy
    - » Osteopathic manipulation
  - Limits indications for back surgery

Categorization of Submitted Questions



Session 1: Provider/Patient Communication and Dissemination Strategies

For patients with noncancer pain who are new or previous users of opioids, what is the comparative effectiveness of various provider and patient communication and dissemination strategies to promote guideline concordant care on reducing the rate of inappropriate provider initiation of opioids for pain management?

Sessions 2 and 4: Health System Organizational Strategies

What is the comparative effectiveness of health system strategies that include elements of prescription monitoring and physician feedback combined with expanding access to alternative methods for pain management compared with usual care on reducing rates of inappropriate provider initiation of opioids for patients with non-cancer pain?

Session 3: Payer Strategies

For patients with non-cancer pain who are new or previous users, what is the comparative effectiveness of insurer-based opioid strategies that include formulary limitations on opioid use, elements of prescription monitoring and physician feedback combined with better coverage of alternative methods for pain management, compared with usual care on reducing rates of inappropriate provider initiation of opioids in primary care for pain and improving patient outcomes?

Question refinement process

- **Step 1: Identify Priority Questions from the Discussion List**
  - » PCORI Research Prioritization Criteria
  - » May consider additional questions not on the list
- **Step 2: Refine the top 1-2 research questions**
  - » Expanded discussion of specific populations of interest, health decisions, and treatments
  - » Consideration of study design, challenges to conducting research on specific question, and ongoing work in the field
- **Step 3: Report back after lunch**

PCORI Research Prioritization Criteria

- **Patient-Centeredness**: is the comparison relevant to patients, their caregivers, clinicians or other key stakeholders and are the outcomes relevant to patients?
- **Impact of the Condition on the Health of Individuals and Population**s: Is the condition or disease associated with a significant burden in the US population, in terms of disease prevalence, costs to society, loss of productivity or individual suffering?
- **Assessment of Current Options**: Does the topic reflect an important evidence gap related to current options that is not being addressed by ongoing research.
- **Likelihood of Implementation in Practice**: Would new information generated by research be likely to have an impact in practice? (E.g. do one or more major stakeholder groups endorse the question?)
- **Durability of Information**: Would new information on this topic remain current for several years, or would it be rendered obsolete quickly by new technologies or subsequent studies?

Break out Groups

Dial in Number: 1 (866) 640-4044 International 1 (678) 302-3544

Session 1- Provider/Patient-level Strategies
Washington Ballroom
Participant Code: 134531
Facilitator: David Gastfriend
Slide Presenter: Andrea Brandau
Notetaker: Olivia Hoppe

Session 2- Comprehensive System-level Strategies (a)
Pentagon I & II
Participant Code: 109712
Facilitator: Erin Krebs
Slide Presenter: Layla Lavasani
Notetaker: Katie Hughes

Session 3- Payer Strategies
Madison
Participant Code: 628131
Facilitator: Doris Lotz
Slide Presenter: Penny Mohr
Notetaker: Alex Hartzman

Session 4- Comprehensive System-level Strategies (b)
Van Buren
Participant Code: 465469
Facilitator: Caleb Alexander
Slide Presenter: Carolyn Mohan
Notetaker: Geeta Bhat

Breakout sessions—Critical Gaps in Evidence

10:30 – 12:30pm

LUNCH

12:30 – 1:00pm

Report Back and Discussion: Priority Research Questions for PCORI and Justification

Facilitator: Linda Porter

Session 1 Questions

(1.2) What is the comparative effectiveness of different strategies of shared decision-making to educate patients about the relative risks and benefits of opioids and alternative treatments on opioid initiation and patient outcomes?

(1.4) What is the comparative effectiveness of different clinical decision support tools integrated into EHRs and on-line portals to enhance pain management on opioid prescribing and patient outcomes?

Session 2 Questions

(2) What is the comparative effectiveness of different health system strategies that aim to change opioid prescribing behavior and/or expand access to non-opioid methods for pain management with the goal of improving patient function and quality of life outcomes while reducing patient harm?

Session 3 Questions

(3.2) For patients with acute pain who are new, or repeat users of opioids, what is the comparative effectiveness of improving access to non-pharmacological treatment modalities (like physical therapy, Biofeedback, Cognitive Behavioral Therapy, (CBT), or Yoga) in primary care on reducing rates of inappropriate provider initiation of opioids for pain and improving patient outcomes?

(3.3) What is the comparative effectiveness of changing the reimbursement/incentive or disincentive structures and other payer tools for opioids versus nonpharmacologic options versus usual care?

Session 4 Questions

(4.4) What is the comparative effectiveness of alternative medication management + case management to connect patients with relevant services for pain management versus expanding access to alternative non-pharmacologic therapies to reduce pain severity at point of care (e.g., embedded acupuncture services, CBT, PT/exercise therapy, yoga?)

(4.5) What is the comparative effectiveness of mandatory use of patient-reported assessment tools, coupled with physician feedback at every clinical encounter vs. usual care on opioid initiation and continuation, patient self-management, pain, and function?

Voting

2:15 – 2:30pm

Tally Sheet for Voting

Providing the corresponding question number, please rank the questions according to your first, second, and third choices.

Ranking Order	Question Number
First	
Second	
Third	

Outcome of Vote and Discussion

Top three questions (about equal number of votes)

- **(1.1)** What is the comparative effectiveness of different strategies of shared decision-making to educate patients about the relative risks and benefits of opioids and alternative treatments on opioid initiation and patient outcomes?

- **(2.1)** What is the comparative effectiveness of different health system strategies that aim to change opioid prescribing behavior and/or expand access to non-opioid methods for pain management with the goal of improving patient function and quality of life outcomes while reducing patient harm?

- **(3.1)** For patients with acute pain who are new, or repeat users of opioids, what is the comparative effectiveness of improving access to non-pharmacological treatment modalities (like physical therapy, Biofeedback, Cognitive Behavioral Therapy, (CBT), or Yoga) in primary care on reducing rates of inappropriate provider initiation of opioids for pain and improving patient outcomes?

Closing Remarks

Steve Clauser, PhD
Director, Improving Healthcare Systems
PCORI

Closing remarks

- Meeting summary will be distributed in a few weeks
- Prioritized questions and deliberations from workshop will be shared with PCORI leadership
- PCORI governance will determine next steps

Thank You