

Providers Clinical Support System

#### Approach to Use of Opioids in Patients with Low Back Pain – Revised

#### Roger Chou, MD, FACP

Professor of Medicine Oregon Health & Science University Director, the Pacific Northwest Evidence-based Practice Center



## Roger Chou, MD, Disclosures

 Dr. Chou has no relevant financial relationship(s) with ACCME defined commercial interests to disclose.

The content of this activity may include discussion of off label or investigative drug uses. The faculty is aware that it is their responsibility to disclose this information.



#### **Target Audience**

 The overarching goal of PCSS is to train a diverse range of healthcare professionals in the safe and effective prescribing of opioid medications for the treatment of pain, as well as the treatment of substance use disorders, particularly opioid use disorders, with medication-assisted treatments.



#### **Educational Objectives**

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

- Describe the benefits and harms of opioids in patients with low back pain.
- Describe an evidence-based approach to the use of opioids for low back pain.





Mr. S. is a 57 year old with LBP x 2 years, no specific inciting event

- No associated leg pain or other neurological symptoms
- Pain slowly worsening, to the point of not being able to walk more than 2 to 3 blocks, rated 7/10 most days
- Continues to golf most weekends, but riding cart now
- Working as an engineer
- X-rays show lumbar disc degeneration and facet joint arthropathy
- Tried acetaminophen and NSAIDs and has undergone PT
- "What do you think about trying an opioid doc?"





- Low back pain is the 5<sup>th</sup> most common reason for U.S. office visits, and the 2<sup>nd</sup> most common symptomatic reason
  - Lifetime prevalence for any LBP episode: Up to 84%
  - Point prevalence: 12% to 30%
  - >16 million LBP office visits/year
  - 5% of PCP visits are for LBP
- >\$100 billion dollars in total health care expenditures for LBP in U.S. (1998)
  - Pharmacy costs >20% of total health care expenditures
- Large indirect costs
  - Low back pain is the most common cause for activity limitations in persons under the age of 45



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# Prevalence of Chronic LBP is Rising

Percentage of North Carolina adults with chronic low back pain





# **Opioid Prescribing Patterns**

- Increased use of opioids in patients with LBP
  - Prescribing rates more than doubled (108% increase) from 1997 through 2004
  - Increased prescribing resulted in 423% inflation-adjusted increase in expenditures
  - >50% of regular prescription opioid users have LBP
- High proportion of patients with LBP prescribed opioids
  - Opioids are the most commonly prescribed medication for LBP
  - 42% in a prospective study of patients with work-related LBP
  - 61% in large health maintenance organization with LBP received opioids, 19% chronic use
- Adverse selection: Pts more likely to be harmed by opioids are more likely to be prescribed them



#### Increasing Rates of Opioid Use

**b** Opioid analgesic prescriptions for spine problems





# Which Patients with LBP are Treated with Opioids?

- Variations not explained by differences in pain severity
- Factors associated with increased likelihood of opioid prescribing:
  - Greater psychological distress
  - Poorer health and unhealthy lifestyles
  - Use of sedative-hypnotics
  - Similar factors associated with use of high-dose opioids
- Data indicate use of opioids related to presence of psychosocial factors that put patients at increased use for adverse opioid-related drug events – "Adverse selection"



# Benefits of Opioid Therapy for LBP

- Benefits for chronic LBP are small to moderate
  - Randomized trials found opioids associated with modest short-term effects on pain
  - For chronic pain in general, more evidence, with benefits in randomized trials averaging ~20% for short-term (<12 weeks) pain relief
  - Until recently, no studies on long-term benefits of opioid therapy vs. no opioid
  - Effects on function not consistently demonstrated in randomized trials
  - Some observational studies suggest opioid use associated with poorer functional outcomes
- No placebo-controlled trials of opioids for acute LBP
  - Opioid generally accepted as effective for various types of acute pain



### **SPACE** Trial

# RCT of opioid therapy vs. non-opioid therapy for chronic LBP and OA pain (2017)

- One year VA trial in primary care, n=240
  - Open-label for patients and clinicians, assessment masked
  - All patients received individualized medication management with stepped care approach within a collaborative telecare pain management model
- Opioid therapy: Step 1 IR morphine, oxycodone, or hydrocodone/acetaminophen, with dose titration; step 2 SR morphine or oxycodone; step 3 transdermal fentanyl

• MED/day at 12 mos: 12% 105-120, 23% 75-105, 43% 25-75, 21% 0-25

- Non-opioid therapy: Step 1 acetaminophen or NSAID, step 2 adjuvant oral meds (nortriptyline, amitriptyline, gabapentin) and topical analgesics (capsaicin, lidocaine), step 3 pregabalin, duloxetine, gabapentin
- At 12 mos, no difference in mean function; pain worse in opioid group
  - Clinically significant improvement: Brief Pain Inventory [BPI] interference 59% vs. 61%; BPI severity 41% vs. 54% (p=0.007)
  - Opioids associated with more adverse symptoms; no deaths or OUD



#### **SPACE Trial**



#### **SPACE** Trial

#### Pain interference with function







### Misuse Potential of Opioids

In primary care settings, rates of misuse range from 4% to 26%

- Definitions inconsistent across studies and behaviors evaluated vary in seriousness
- Poorly standardized methods to detect these outcomes
- Data from efficacy trials underestimate risks due to patient selection methods
- One study (n=801) based on standardized, 2 hour interviews of patients on chronic opioids
  - 26% purposeful oversedation
  - 39% increased dose without prescription
  - 8% obtained extra opioids from other doctors
  - 18% used for purposes other than pain
  - 12% hoarded pain medications



### Prescription Drug Overdoses

- Large increases in prescription opioid overdoses nationally
- Overdose trends parallel opioid prescribing trends
  - ~15,000 cases/year
  - In some states, opioid-related overdose deaths exceed MVA's as most common cause of accidental death
  - Exceed deaths from heroin and cocaine combined



# Rates of prescription painkiller sales, deaths and substance abuse treatment admissions (1999-2010)



SOURCES: National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009



### Risk of prescription opioid overdose



Source: National Center for Health Statistics, CDC Wonder



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Rates are per 100,000 population age-adjusted to 2008 U.S. standard population http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm

#### **Risk Factors for Overdose**

- Higher-dose opioid therapy
- Concomitant use of CNS depressants (especially benzodiazepines)
- Recent initiation of opioids
- Psychological comorbidities
- Aberrant drug related behaviors
- Use of methadone
- Certain medical comorbidities (e.g., sleep apnea)
- Active or history of substance use disorder



### Other Harms Associated with Opioids

- Gastrointestinal and central nervous system adverse events
  - Constipation, nausea, sedation, cognitive slowing, and others
- Hyperalgesia
  - Paradoxical increased sensitivity to pain
  - Prevalence, risk factors and clinical significance not well understood
  - Generally associated with higher doses
- Hypogonadism
  - Evidence limited, temporal relationship between initiation of opioid therapy and hypogonadism unclear
- Falls/fracture risk

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# Use Opioids Only As Part of an Overall LBP Management Plan

- Understand chronic LBP from a biopsychosocial framework
  - Opioids alone do not address psychosocial contributors to pain
  - Benefits of opioids unlikely to exceed an average 20-30% reduction in pain (may be smaller or none)
  - Be clear with patients that opioids generally do not eliminate pain, and are just part of a comprehensive management plan
  - Use opioids in conjunction with therapies that address psychosocial factors
- For acute LBP, the natural history is very favorable
  - ~85% of patients improve substantially in the first month
  - Opioid use in acute LBP associated with poorer functional outcomes and subsequent long-term use
  - Selective opioid use for acute severe pain on a time-limited basis, for short-term symptomatic relief



### 2016 CDC Guidelines

#### **Recommendation #1**

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.
- Consider opioid therapy only if expected benefits are anticipated to outweigh risks to the patient.
- If opioids are used, combine with appropriate nonpharmacologic therapy and nonopioid pharmacologic therapy.



#### 2017 American College of Physicians/American Pain Society guideline

#### Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline

Roger Chou, MD; Richard Deyo, MD, MPH; Janna Friedly, MD; Andrea Skelly, PhD, MPH; Robin Hashimoto, PhD; Melissa Weimer, DO, MCR; Rochelle Fu, PhD; Tracy Dana, MLS; Paul Kraegel, MSW; Jessica Griffin, MS; Sara Grusing, BA; and Erika D. Brodt, BS

#### Systemic Pharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline

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#### Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians

Amir Qaseem, MD, PhD, MHA; Timothy J. Wilt, MD, MPH; Robert M. McLean, MD; and Mary Ann Forciea, MD; for the Clinical Guidelines Committee of the American College of Physicians\*



#### 2017 American College of Physicians/American Pain Society guideline

- Emphasis on nonpharmacologic over pharmacologic therapies, particularly for chronic LBP
- Stronger cautions regarding use of opioids
- Acetaminophen no longer recommended for acute LBP
- Recommends use of several "active" mind-body interventions (yoga, Tai Chi, mindfulness-based stress reduction)



# Management Approach to LBP

- Emphasis on self-care and improving function
  - Advise patients to remain active, coping strategies, relaxation techniques
  - Active therapies: Exercise therapy, CBT, yoga, mindfulness, interdisciplinary rehabilitation
- Identify and address psychosocial contributors to pain
  - Depression, anxiety, PTSD, maladaptive coping behaviors (fear avoidance, catastrophizing), sleep disturbance, stressors
  - CBT, pharmacological therapy
- Utilize other non-pharmacological therapies
  - Spinal manipulation, acupuncture, massage
- Medications adjunctive therapy: First-line NSAIDs
  - Recent RCT showed no benefits of acetaminophen for acute LBP
  - Second-line options: skeletal muscle relaxants (acute LBP) and antidepressants (chronic LBP)

#### Reserve opioids for patients who don't respond to first-line therapies, or selected cases with very severe symptoms



### Will this Patient Develop Persistent Disabling LBP?

Predictor	Positive likelihood ratio for persistent disabling LBP at 1 year: median (range)
Nonorganic signs	3.0 (1.7-4.6)
Maladaptive pain coping behaviors	2.5 (2.2-2.8)
Baseline functional impairment	2.1 (1.2-2.7)
Psychiatric comorbidities	2.2 (1.9-2.3)
Low general health status	1.8 (1.1-2.0)
Variables related to work environment, baseline pain, presence of radiculopathy	Around 1.5
History of prior LBP episodes, demographic variables (age, sex, overweight, smoking, education)	Not predictive



# Targeting Patients at Risk for Chronicity

#### STarT Back Trial

- 1573 UK patients with LBP (+/- radiculopathy)
- Randomized to stratified care based on prognosis (low, medium, or high-risk) or usual care
  - Low-risk intervention: educational video and booklet
  - Medium and high-risk interventions: referred for psychologically informed physiotherapy (3 vs. 9 days of additional training)
- Stratified care more effective than usual care for function (1.8 points at 4 months and 1.1 pts at 12 months); also cost effective
- STarT Back approach being tested in the U.S.



#### The Keele STarT Back Screening Tool

Patient name: \_\_\_\_\_ Date: \_\_\_\_\_

Thinking about the last 2 weeks tick your response to the following questions:

		Disagree 0	Agree 1
1	My back pain has spread down my leg(s) at some time in the last 2 weeks		
2	I have had pain in the shoulder or $\mathbf{neck}$ at some time in the last 2 weeks		
3	I have only walked short distances because of my back pain		
4	In the last 2 weeks, I have <b>dressed more slowly</b> than usual because of back pain		
5	It's not really safe for a person with a condition like mine to be physically active		
6	Worrying thoughts have been going through my mind a lot of the time		
7	I feel that my back pain is terrible and it's never going to get any better		
8	In general I have not enjoyed all the things I used to enjoy		
8	In general I have <b>not enjoyed</b> all the things I used to enjoy		

9. Overall, how bothersome has your back pain been in the last 2 weeks?

Not at all	Slightly	Moderately	Very much	Extremely	
0	0	0	1	1	
Total score (all 9):		Sub Scor	Sub Score (Q5-9):		

### Scoring the STarT Back Screening Tool





# Selecting Patients for Opioid Therapy

- Risk assessment is critical before using opioids
  - Helps inform the decision of whether to initiate opioids
  - Helps determine the intensity of follow-up and monitoring
- Assessment of abuse potential required in all patients considered for opioids
  - Strongest predictor is personal or family history of substance use disorder
  - The Opioid Risk Tool allows clinicians to categorize patients as low, medium, or high risk for aberrant drug-related behaviors based on a simple point system
  - Additional validation needed for risk assessment instruments
  - Avoid opioids in patients at high risk; consider alternatives in patients at medium risk; address identified risk factors
- Also consider potential benefits, and other potential harms (i.e. respiratory depression in patients with sleep apnea) when making decision to start opioids



# Opioid Risk Tool (ORT)

#### Administration

 Prior to initiation of opioid therapy, in order to predict opioid misuse on long-term opioid therapy

#### <u>Scoring</u>

- 0-3: low risk (6%)
- 4-7: moderate risk (28%)
- > 8: high risk (> 90%)

Mark each box that applies	Female	Male	
1. Family history of substance abuse			
Alcohol	□ 1	□ 3	
Illegal drugs	□ 2	□ 3	
Prescription drugs	□ 4	□4	
2. Personal history of substance abuse			
Alcohol	□ 3	□ 3	
lllegal drugs	□ 4	□4	
Prescription drugs	□ 5	□ 5	
3. Age (mark if between 16-45 yrs)	□1	□1	
4. History of preadolescent sexual abuse	□ 3	0 🗆	
5. Psychological disease			
ADO, OCD, bipolar, schizophrenia	□ 2	□ 2	
Depression	□ 1	□1	
Scoring totals			
Depression Scoring totals			



# Initiation and Titration of Opioids

- View initial course of treatment as a short-term, therapeutic trial
  - The decision to proceed (or continue) with long-term opioid therapy should be a conscious one
  - Determine achievable functional goals in order to assess benefits
  - Do not continue long-term opioid therapy in patients who are not benefitting
- Start at low doses and titrate cautiously, to reduce risk of accidental overdose
  - Particular caution with methadone (long and unpredictable half-life)



### Set Functional Treatment Goals

# Goals should be actionable, measurable, and achievable

- Regular assessments of whether patients are achieving treatment goals, in order to guide treatment decisions
  - Consider discontinuation in patients not making progress towards meeting goals
- Not achievable: "I want to be pain-free."
- Actionable, measurable, and achievable: "I want to be able to walk my dog 20 minutes a day, 4-5 times a week."



#### **Dose Escalations**

- Opioids for chronic pain often prescribed with no ceiling dose
- Risk of overdose begins to increase at <50 mg morphine equivalents/day, and continues to rise in dose-dependent fashion
- Very limited data on effectiveness of opioids at higher doses
  - Patients who do not respond to lower doses often will not respond at higher doses
- Only prescribe higher doses in patients with clear improvements in pain and function and with close monitoring
  - 2016 CDC guideline: "Caution" with doses >50 MED/day, "avoid" >90 MED/day
- Slow dose increases, with follow-up after changes
- Some evidence that dose threshold policies reduce high-dose prescribing rates and overdose



### Prescribed opioid dose (MME) and risk of overdose

#### Odds Ratio or Hazard Ratio for Overdose Relative to 1 to <20 MME





# Selection of Opioids

- No evidence that long-acting opioids are safer or less prone to abuse than short-acting opioids
  - Long-acting opioids may result in fewer drug peaks associated with euphoria, but decreased risk of addiction or abuse has not been demonstrated
- No evidence that round-the-clock, scheduled dosing safer or less prone to abuse than PRN dosing
  - Use of round-the-clock, scheduled dosing may contribute to development of tolerance and dose escalations
- Recommend initiation with short-acting opioids
  - Safer in opioid-naïve patients, easier to titrate doses
  - Can transition to long-acting opioids, but no compelling reason to do so in patients without aberrant behaviors and good response on short-acting meds



# **Risk Mitigation Strategies**

- Informed consent required in all patients
- Long-term opioid therapy management plan recommended by guidelines
  - Components include: Follow-up expectations, single prescriber and pharmacy, no early or off-hour fill requests, expectations for monitoring, use of non-opioid therapies, functional goals, indications for tapering or discontinuation
  - Helps define expectations as well as assist other providers who see patient
- Follow-up generally recommended q3-6 months, may be more frequent in high risk patients
- Consider dispensing weekly or biweekly rather than monthly in higher risk patients
  - Some data suggesting shorter duration between prescription refills (smaller amounts dispensed) associated with shorter time off work



# Urine Drug Tests

- Self-report unreliable and behavioral observational detect only some problems
- Urine drug tests provide objective information regarding
  - Adherence to opioid plan of care
  - Use or non-use of illicit substances or unprescribed medications
  - May improve adherence to opioid plan of care
- Perform at baseline and periodically
  - 1-2 times/year for low-risk patients; 3-4 times/year for higher risk
  - Random, scheduled, and /or when concerns arise
  - Discuss expected findings with patient prior to testing
  - Consult with toxicologist/clinical pathologist before acting if patient disputes findings
    - Screening tests requires confirmation
  - Dedicated deceivers can beat the system



# Prescription Drug Monitoring Programs

- Available now in almost all states
  - >20 states require clinicians to access prior to prescribing controlled substances
- Studies show that use of PDMPs can identify cases of diversion, doctor shopping and flag unsafe prescribing practices
  - Effects on clinical outcomes (e.g., overdose) not known
- Use variable and generally suboptimal
- PDMPs vary in who can access, information not available across states, functionality variable



### Avoid Opioids and Benzo's

- Concomitant benzodiazepine use associated with markedly increased risk of opioid overdose
  - Other medications with respiratory depressant effects may also be associated with similar risks
- Taper benzodiazepines gradually
- Offer evidence-based psychotherapies for anxiety
  - cognitive behavioral therapy
  - anti-depressants approved for anxiety
  - other non-benzodiazepine medications approved for anxiety
- Coordinate care with mental health professionals



#### Naloxone

- Opioid antagonist that can rapidly reverse opioid overdose; most overdose episodes are witnessed
  - Highly effective in addiction settings
  - Some evidence of effectiveness in chronic pain settings
    - One observational study found that co-prescribing of naloxone to primary care patients prescribed opioids associated with 47% fewer opioid-related ED visits at 6 months and 63% fewer visits at 1 year compared with no naloxone<sup>a</sup>
- CDC recommends for all patients on ≥50 MED/day, or other risk factors for overdose
  - Consider for all patients prescribed opioids
- Available in FDA-approved IM and IN formulations, also used off-label



### **Opioid-deterrent Formulations**

Opioid-deterrent formulations recently approved by FDA

- Designed to be tamper-resistant or co-formulated with medications that reverse opioid effects or produce noxious side effects when tampered with
- Effectiveness for reducing misuse/substance abuse and improving clinical outcomes yet to be established
  - Potential unintended consequences (use of illicit opioids)
- Likely to be primarily effective in patients who crush or inject oral opioids
  - May not improve safety related to accidental overdose from oral ingestion
  - Does not remove the need to perform appropriate risk assessment and monitoring when using opioids





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# Discontinuing Opioids or Restructuring Therapy

#### Have an "exit strategy" when starting opioids for LBP

- Clear understanding of circumstances that will lead to discontinuation
  - Patients not benefitting from opioids in terms of reduced pain AND improved function
  - Patients experiencing harms or unable to safely manage opioids
- Plan for tapering opioids and managing withdrawal

Patients may require restructuring of therapy to safely continue opioids

- Lowering dose
- Intensified monitoring
- Specialty consultation

#### Continue to manage patients for pain with non-opioid therapies

- Interventions to address psychological comorbidities and maladaptive coping
- Focus on improving function



# **Tapering Opioids**

- Periodically perform risk-benefit assessment to inform tapering decisions, including the following factors:
  - Presence of opioid use disorder and misuse behaviors
  - Prior overdose episodes
  - Opioid dose
  - Failure to improve or meet treatment goals
  - Use of concomitant respiratory depressants (e.g., benzodiazepines)
- Initiate taper when benefits outweighed by risks
  - Offer taper for patients at high doses (e.g., MED >90/day)
- Some evidence shows that pain, function, and quality of life may improve with opioid dose reduction
  - Optimal tapering protocol uncertain; some patients may require prolonged tapers
  - Focus on dose reductions and reducing risk rather than specific dose thresholds
  - Strategies for difficult tapers: Referral to interdisciplinary pain program or addiction specialty, buprenorphine-assisted tapers, taper support programs



# **Opioids for Acute Low Back Pain**

- Opioids generally considered effective for acute pain
  - But, recent data indicates that opioids may be no more effective than an NSAID alone for acute pain
    - In LBP adding oxycodone/acetaminophen to an NSAID did not improve pain or function at 1 week<sup>1</sup>
- Use of opioids for "minor" pain associated with increased risk of long-term use
  - Versus no opioid use, opioid within 7 days of minor surgery associated with 44% increased risk of use at 1 year<sup>2</sup>
- Prescribing excessive quantities of opioids for acute pain resulting in leftover opioids
  - Source of diversion and unprescribed use
- More judicious use of opioids for acute pain
  - If used, limit opioids to a 3-7 day supply for most acute pain
  - Research on doses of opioids prescribed/used for acute LBP is ongoing



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### **Opioids and Low Back Pain**

- Consider opioids only in the context of an overall pain management plan
  - Opioids do not address the psychosocial contributors to pain
- Not recommended as first-line treatment
  - Evidence on effectiveness for LBP limited and suggest at most small short-term benefits
  - Serious harms, including overdose and OUD
  - Consider only after performing risk assessment and with appropriate monitoring
    - Duration-limited trial of therapy
  - Dose-dependent overdose risks
    - Unclear benefits of higher doses
    - Caution with doses >50 MED/day and avoid doses >90 MED/day



#### Case - Risk Assessment

- Mr. S. has no personal or family history of substance abuse
- No history of depression or other psychological disorders
- No serious comorbid conditions that are contraindications to opioid therapy
- Opioid Risk Tool score: 0
- Urine drug test negative
- Assessed risk: Low



### Case - Management Plan

- At 8 week follow-up, pain still at 5-6/10
- Low-dose opioid therapy (oxycodone 5 mg twice daily) initiated
- At 12 week follow-up, pain decreased to 4/10, no aberrant behaviors
- Plan: Continue opioid therapy at the same, low dose, follow-up in 2 months



### Case - Management Plan

- Set goal of walking 30 minutes 4 times a week
- Longer term goal walking 9 holes of golf
- Exercise therapy recommended, recommended continue low-impact activities
- At 4 week follow-up, pain decreased from 7/10 to 6/10, pt engaged in exercise therapy
- Able to walk 20-30 minutes 4 times a week
- Initiated duloxetine



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## **PCSS Mentoring Program**

- PCSS Mentor Program is designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid addiction.
- PCSS Mentors are a national network of providers with expertise in addictions, pain, evidence-based treatment including medicationassisted treatment.
- 3-tiered approach allows every mentor/mentee relationship to be unique and catered to the specific needs of the mentee.
- No cost.

#### For more information visit: http://www.pcssNOW.org/mentor



### **PCSS Discussion Forum**



http://pcss.invisionzone.com/register





Providers System

**PCSS** is a collaborative effort led by the American Academy of Addiction Psychiatry (AAAP) in partnership with:

American Academy of Family Physicians	American Psychiatric Association
American Academy of Neurology	American Society of Addiction Medicine
Addiction Technology Transfer Center	American Society of Pain Management Nursing
American Academy of Pain Medicine	Association for Medical Education and Research in Substance Abuse
American Academy of Pediatrics	International Nurses Society on Addictions
American College of Emergency Physicians	American Psychiatric Nurses Association
American College of Physicians	National Association of Community Health Centers
American Dental Association	National Association of Drug Court Professionals
American Medical Association	Southeastern Consortium for Substance Abuse Training
American Osteopathic Academy of Addiction Medicine	



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pcss@aaap.org

Funding for this initiative was made possible (in part) by grant no. 5U79TI026556-03 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.