Reversing the opioid epidemic and improving outcomes for your pain patients

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PCSS-O is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: Addiction Technology Transfer Center (ATTC), American Academy of Neurology (AAN), American Academy of Pain Medicine (AAPM), American Academy of Pediatrics (AAP), American College of Physicians (ACP), American Dental Association (ADA), American Medical Association (AMA), American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA), American Society for Pain Management Nursing (ASPMN), International Nurses Society on Addictions (IntNSA), and Southeast Consortium for Substance Abuse Training (SECSAT).

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This material has been reviewed by the lead Clinical Expert on the PCSS-O grant, co-faculty, AAN staff, and PCSS-O staff. Webinars will be available on-demand for participants unable to make the live event.
"To write prescriptions is easy, but to come to an understanding with people is hard."

--Franz Kafka, “A Country Doctor”
You will not be able to effectively alter epidemic if you don’t understand how the epidemic began

- By the late 1990s, at least 20 states passed new laws, regulations, or policies moving from near prohibition of opioids to use without dosing guidance-stated goal was to provide a safe “safe haven” for prescribing
  - WA law: “No disciplinary action will be taken against a practitioner based solely on the quantity and/or frequency of opioids prescribed.” (WAC 246-919-830, 12/1999)

- Laws were based on weak science and good experience with cancer pain: Thus, no ceiling on dose and axiom to use more opioid if tolerance develops

- Pain as 5th vital sign campaign and JOINT COMMISSION/CMS satisfaction survey

WAC-Washington Administrative Code
Randomized trial Re effectiveness of escalating dose

- RCT of “hold the line” vs escalating dose strategies
- N=135, parallel group pragmatic study
- No change in any primary pain or function outcome
- 27% discharged due to misuse/non-compliance

*Naliboff et al, 2011 (FEB); 12: 288-96
Portenoy and Foley
Pain 1986; 25: 171-186

• Retrospective case series chronic, non-cancer pain
• N=38; 19 Rx for at least 4 years
• 2/3 < 20 mg MED/day; 4> 40 mg MED/day
• 24/38 acceptable pain relief
• No gain in social function or employment could be documented

By 2006, 10,000 patients in WA public programs were on >100 mg MED/day-data from public programs computerized databases

How many chronic pain patients in your practice are on doses over 100 mg/day? How many are on combinations of opioids and benzodiazepines or sedative hypnotics?
Evidence of efficacy of COAT

• Furlan et al 2011 systematic review (2011; Pain Res Manag 16: 337-351)
  - 62 RCTs
    - 51.6% adequately randomized
    - N=11,927 randomized, but only 7807 (65%) finished trials
    - 41/62 RCTs involved at least one author associated with pharmaceutical industry
    - All trials shorter term (<3 months)
    - Enriched enrollment trials overestimate benefit and underestimate adverse effects
    - Pain improvement moderate but function improvement small [pain effect size medium (0.58); function effect size low (0.34)]
    - Doses used in practice far in excess of those used in RCTs
Evidence of effectiveness of COAT

The Agency for Healthcare Research and Quality’s (AHRQ) recent draft report, “The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain,” which focused on studies of effectiveness measured at > 1 year of COAT use, found insufficient data on long term effectiveness to reach any conclusion, and “evidence supports a dose-dependent risk for serious harms”. (AHRQ 2014; Chou et al, Annals Int Med, 13 Jan 2015).
The worst man-made epidemic in modern medical history—in my opinion

- Over 175,000 deaths
- Many more hundreds of thousands of overdose admissions
- Millions addicted and/or dependent
- Spillover effect to SSDI² and to heroin (40% new initiates started on Rx opioids)

1. Personal communication with C Jones, CDC
People with abuse or dependence on:

- Alcohol: 2x
- Marijuana: 3x
- Cocaine: 15x
- Rx Opioid Painkillers: 40x

More likely to have heroin abuse or dependence
Risk/Benefit of Opioids for Chronic Non-Cancer Pain
(Franklin; Neurology; Sept 2014 Position paper of the AAN)

[Diagram showing a balance scale with Effectiveness on one side and various risks on the other, including Mortality, Overdose morbidity, Serious adverse events, Dependence/Addiction, Life long disability, Loss of family and community.]
Because of the paucity of evidence of effectiveness with chronic use, and poor risk profile, esp. for dependence and addiction, opioids should not be used routinely for the treatment of routine musculoskeletal conditions, headaches or fibromyalgia*

WA DLI opioid guidelines, 2013 [http://1.usa.gov/1nYlarL](http://1.usa.gov/1nYlarL)

- Chronic LBP: Chaparro et al, Spine 2014; 39: 556-63
- Fibromyalgia: Gaskell et al, Cochrane Review; 2014: CD010692
Why not prescribe for chronic low back pain?

• Alternative treatments, particularly programs that take a psycho-physical approach, have a strong evidence base
• Opioids generally are deactivating and not activating
• Reduced prescribing for non-specific back pain would significantly reduce overall prescribing and availability, and thus safety - public health benefit
• Eliminating prescribing for common indications that have failed would be a step towards identifying cases that do derive benefit

*Slide courtesy Jane Ballantyne, MD; opinion of Dr Ballantyne*
Early opioids and disability in WA WC. Spine 2008; 33: 199-204

• Population-based, prospective cohort
• N=1843 workers with acute low back injury and at least 4 days lost time
• Baseline interview within 18 days (median)
• 14% on disability at one year
• Receipt of opioids for > 7 days, at least 2 Rxs, or > 150 mg MED doubled risk of 1 year disability, after adjustment for pain, function, injury severity
Enduring adaptation produced by established behaviors
Addiction criteria may be different for pain patients on chronic opioids

For the illicit drug user:
- Procurement behaviors

For the pain patient — much more complex
- Continuous opioid therapy may prevent opioid-seeking
- Memory of pain, pain relief, and also euphoria
- Even if the opioid-seeking appears as seeking pain relief, it becomes an adaptation that is difficult to reverse
- It is hard to distinguish between drug-seeking and relief-seeking

High Risk Populations

- People taking high daily doses of opioids
- People who “doctor shop”
- People using multiple abuseable substances like opioids, benzodiazepines, other CNS depressants, illicit drugs
- Low-income people and those living in rural areas
- Medicaid populations
- People with substance abuse or other mental health issues


Responding to the EVIDENCE: Morphine Equivalent Dose RELATED RISK

- Risk of adverse ± overdose event increases at >50 mg MED/day
- Risk increases greatly at ≥100 MED/day
Opioid Dosing Policies Since 2007

• 2007: WA AMDG recommended consultation at 120 mg/day MED
• 2009: CDC recommended consultation at 120 mg/day MED
• 2010: WA ESHB 2876 directed DOH Boards and Commissions to establish dosing guidance and best practices
• 2012: CT workers comp recommended a threshold at 90 mg/day MED
• 2013: OH Medical Board recommended a threshold at 80 mg/day MED http://www.med.ohio.gov/pdf/NEWS/Prescribing%20Opioids%20Guidlines.pdf
• American College of Occupational and Environmental Medicine recommended a threshold at 50 mg/day MED
• 2014: CA Medical Board recommended a yellow flag at 80 mg/day MED http://www.mbc.ca.gov/Licensees/Prescribing/Pain_Guidelines.pdf
• 2014: CO Department of Regulatory Agencies recommended a threshold at 120 mg/day MED http://1.usa.gov/1DNPaxT
• 2015: Minnesota Dept of Human Resources limits all opiate prescriptions to a maximum dose of 120 mg/day MED; http://bit.ly/1RA87AF
• CDC guidelines-expected release data Jan 2015
Guidelines

- Improve prescribing and treatment
- Basis for standard of accepted medical practice for purposes of licensure board actions
- Several evidence/consensus guidelines available
- Common themes among guidelines
Washington Agency Medical Directors’ Opioid Dosing Guidelines

- Developed with clinical academic pain experts in 2006-released online April 2007
- Part I - If patient has not had clear improvement in pain AND function at 120 mg MED (morphine equivalent dose), “take a deep breath”
  - If needed, get one-time pain management consultation (certified in pain, neurology, or psychiatry)
- Part II - Guidance for patients already on very high doses >120 mg MED

www.agencymeddirectors.wa.gov
Guidance for Primary Care Providers on More Cautious Use of Opioids for Chronic Non-cancer Pain

- Establish an opioid treatment agreement
- Screen for
  - Prior or current substance abuse
  - Depression
- Use random urine drug screening judiciously
  - Shows patient is taking prescribed drugs
  - Identifies non-prescribed drugs
- Do not use concomitant sedative-hypnotics
- Track pain and function to recognize tolerance
- Seek help if dose reaches 120 mg MED, and pain and function have not substantially improved
- Use PDMP initially and for monitoring

http://www.agencymeddirectors.wa.gov/opioiddosing.asp
MED, Morphine equivalent dose
Open-source Tools Added June 2010
Update of AMDG Opioid Dosing Guideline

- Opioid Risk Tool: Screen for past and current substance abuse
- CAGE-AID screen for alcohol or drug abuse
- Patient Health Questionnaire-9 screen for depression
- 2-question tool for tracking pain and function
- Advice on urine drug testing

**OPIOID DOSE CALCULATOR**

<table>
<thead>
<tr>
<th>Opioid (oral or transdermal)</th>
<th>Mg per day</th>
<th>Morphine equivalents</th>
</tr>
</thead>
<tbody>
<tr>
<td>codeine</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>fentanyl transdermal (in mcg/hr)</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>hydrocodone</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>hydromorphone</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>methadone</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>up to 20mg per day</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>21 to 40mg per day</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>41 to 60mg per day</td>
<td>50</td>
<td>500</td>
</tr>
<tr>
<td>&gt;60mg per day</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>morphine</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>oxycodone</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>oxymorphone</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td><strong>TOTAL daily morphine equivalent dose (MED)</strong></td>
<td><strong>520</strong></td>
<td></td>
</tr>
</tbody>
</table>

Available as mobile app: http://www.agencymeddirectors.wa.gov/opioiddosing.asp

Source: Washington State Department of Health, Death Certificates
Unintentional Opioid Overdose Deaths
Washington 1995-2014

Source: Washington State Department of Health, Death Certificates
Opioid Poisonings in WA Medicaid

- < 50% have chronic opioid use (> 90 days supply)
- 75% of opioid poisonings occurred in cases with prescribed doses < 120 mg MED
- About 45% have sedative-hypnotics in prior month
- 45% have another medication poisoning diagnosis on the same day
- 10-15% have an alcohol diagnosis on the same day
- Most cases have additional opioid prescriptions after poisoning - ? Make overdose hospitalizations reportable to the WA DOH
- Over 60% of methadone poisonings occurred in cases that did not have a prescription for methadone in the prior year

Interagency Guideline on Prescribing Opioids for Pain

- Developed by the Washington State Agency Medical Directors’ Group (AMDG) in collaboration with an Expert Advisory Panel,
- Actively practicing providers, public stakeholders, and senior state officials.
  - www.agencymeddirectors.wa.gov
Process for Update of WA AMDG Guideline

• April, 2014-Clinical advisers (N=32) invited and assigned to one of three workgroups based on expertise
  ▪ Group 1 addressed opioid use during acute and sub-acute phase, clinically meaningful improvements & alternatives to opioids
  ▪ Group 2 provided guidance on opioid use during perioperative phase
  ▪ Group 3 focused on when to discontinue chronic opioid therapy & initiate addiction treatment

• Drafts circulated to the full Committee for feedback & approval - April 2015

• Final draft published for public comments - May 2015

• Conference on Evidence-Based Pain Care: Featuring a new opioid guideline from the Washington State Agency Medical Directors’ Group - June 2015

• Robert Bree public-private collaborative-endorses AMDG opioid guideline for Statewide use by all payers, hospitals, etc-July, 2015
WA AMDG Guideline Advisory Committee

Clinicians
- David Beck – Grays Harbor Clinic
- Randi Beck – Group Health Cooperative
- Malcolm Butler – Columbia Valley Community Health
- Phillip Capp – Swedish Medical Center Family Practice
- Greg Carter – St. Lukes Rehabilitation
- Dianna Chamblin – Everett Clinic
- Pamela Davies – UW/Seattle Cancer Care Alliance
  Supportive & Palliative Care
- Dermot Fitzgibbon – UW/Seattle Cancer Care Alliance
- Andrew Friedman – Virginia Mason Medical Center
- Debra Gordon – Harborview Anesthesiology & Pain Medicine
- Lucinda Grande – Pioneer Family Practice
- Chris Howe – Valley Medical Center
- Ray Hsiao – Seattle Children’s Hospital/UW Department of Psychiatry and Behavioral Sciences
- Gordon Irving – Swedish Pain and Headache Center
- Joseph Merrill – UW/ Harborview Medical Center
- Patricia Read-Williams – UW Neighborhood Clinics
- Richard Ries – UW/ Harborview Medical Center Division of Addictions
- Andrew Saxon – VA Puget Sound Health Care System/Center of Excellence in Substance Abuse Treatment and Education (CESATE)/UW Addiction Psychiatry Residency Program
- Michael Schatman – Foundation for Ethics in Pain Care
- Mark Sullivan – UW Center for Pain Relief/Department of Psychiatry and Behavioral Sciences
- David Tauben – UW Center for Pain Relief/Division of Pain Medicine
- Greg Terman – UW Department of Anesthesiology
- Stephen Thielke – Seattle VAMC Geriatric Research, Education and Clinical Center
- Michael Von Korff – Group Health Cooperative

Health Plans
- Ken Hopper – Amerigroup, Washington
- James Luciano & Thomas Paulson – Wellpoint Companies
- Mary Kay O’Neill – Coordinated Care/Bree

State Agencies
- Stephen Hammond - DOC
- Kathy Lofy – Dept of Health
- Gary Franklin, Lee Glass, Nicholas Reul & Hal Stockbridge – Labor and Industries
- Dan Lessler & Charissa Fotinos – Medicaid, State employees benefits

Boards and Commissions
- Richard Brantner - MQAC
Because there is little evidence to support long term efficacy of COAT in improving function and pain, and there is ample evidence of its risk for harm, prescribers should proceed with caution when considering whether to initiate opioids or transition to COAT.

Although opioids benefit some patients if prescribed and managed properly for appropriate conditions, from a public health perspective, preventing the next group of Washington residents from developing chronic disability due to unnecessary, ineffective, and potentially harmful COAT is a key objective of this guideline.
Clinically Meaningful Improvement

- Clinically meaningful improvement is improvement in pain and function of at least 30%
- Assess and document function and pain using validated tools at each visit where opioids are prescribed
- Recommend use of quick and free tools to track function and pain
  - PEG: Pain intensity, interference with Enjoyment of life, and interference with General activity
  - Graded Chronic Pain Scale: Pain intensity and pain interference

Tools can be found at:
Clinically Meaningful Improvement

• A decrease in pain intensity in the absence of improved function is not considered meaningful improvement except in very limited circumstances such as catastrophic injuries (e.g., multiple trauma, spinal cord injury, etc).

• Continuing to prescribe opioids in the absence of clinically meaningful improvement in function (CMIF) and pain, or after the development of a severe adverse outcome (e.g., overdose event) is not considered appropriate care. In addition, the use of escalating doses to the point of developing opioid use disorder, as defined by DSM-V, is not appropriate.
Dosing Threshold

• Avoid COAT if the patient has any FDA or clinical contraindications (e.g. current substance use disorder, past opioid use disorder), history of prior opioid overdose, or pattern of aberrant behaviors

• Use great CAUTION at any dose if the patient has certain risk factors (e.g. mental health disorders, current use of benzodiazepines)

• Do NOT prescribe more than 120 mg/day MED without first obtaining a pain management consult, documented absence of risk factors, and documented CMIF

• All prescribed doses of opioids carry risks
Non-Pharmacologic Alternatives

- Do NOT pursue diagnostic tests unless risk factors or specific reasons are identified.
- Use interventions such as listening, providing reassurance, and involving the patient in care.
- Recommend graded exercise, cognitive behavioral therapy, mindfulness based stress reduction (MBSR), various forms of meditation and yoga or spinal manipulation in patients with back pain.
- Address sleep disturbances, BUT, the greatest risk lies in co-prescribing benzodiazepines and sedative/hypnotics with opioids, even at lower doses of opioids.
- Refer patient to a multidisciplinary rehabilitation program if s/he has significant, persistent functional impairment due to complex chronic pain.
Pharmacologic Alternatives

- Use acetaminophen, NSAIDs or combination for minor to moderate pain
- Consider antidepressants (TCAs/SNRIs) and anticonvulsants for neuropathic pain, other centralized pain syndromes, or fibromyalgia
- Avoid carisoprodol (SOMA) due to the risk of misuse and abuse. Do NOT prescribe muscle relaxants beyond a few weeks as they offer little long-term benefit
- Prescribe melatonin, TCAs, trazodone, or other non-controlled substances if the patient requires pharmacologic treatment for insomnia
State Prescription Monitoring Program (PMP)

- Check the PMP with the first prescription to ensure that the patient’s controlled substance history is consistent with report
- Check the PMP if prescribing opioids during the sub-acute phase
- Check the PMP at a frequency based on the patient’s risk category during chronic therapy to identify aberrant behavior such as multiple prescribers or early fills
Opioid Use in Acute Pain (0-6 weeks)

• The use of opioids for non-specific low back pain, headaches and fibromyalgia is not supported by evidence

• Help the patient set reasonable expectations about recovery

• Reserve opioids for pain from severe injuries or medical conditions, surgical procedures or when alternatives are ineffective. If prescribed, shortest duration and lowest necessary dose

• For minor surgical procedures (eg, impacted wisdom tooth)-prescribe no more than 1-3 days short acting opioid

• Consider tapering off opioids by 6 weeks as acute episode resolved or if CMIF hasn’t occurred
Opioid Use in Sub-acute Pain (6-12 weeks)

• Do NOT prescribe opioids if use during acute phase doesn’t lead to

• Screen for depression, anxiety and opioid risk using validated tools

• Avoid prescribing new benzodiazepines and sedative-hypnotics

• Discontinue opioids if there is no CMIF, treatment resulted in severe adverse outcome or patient has a current substance use disorder or a history of opioid use disorder
Opioid Use During Perioperative Period

• Develop a coordinated time-limited treatment plan for managing postoperative pain, including responsible prescriber

• Avoid escalating the opioid dose before surgery

• Do NOT discharge patient with more than 2 weeks supply of opioid. Continued opioid therapy will require appropriate reevaluation by the surgeon

• Taper off opioids added for surgery as surgical healing takes place
  - Major surgeries should be able to be tapered to preoperative doses or lower by 6 weeks
  - For some minor surgeries, it may be appropriate to discharge patients on acetaminophen, NSAIDs only or with a very limited supply of short-acting opioids (e.g. 2-3 days)
Opioid Use in Chronic Pain (>3 months)

- Prescribe COT only if the patient has sustained CMIF, no contraindications and has failed the use of non-opioid alternatives.
- Use extreme caution when prescribing COT in high risk patients.
- Use best (monitoring) practices to ensure effective treatment and minimize potential adverse outcomes.
- Avoid methadone unless the provider is knowledgeable of the drug and is willing to perform additional monitoring.
When to Discontinue Opioids

• Patient request
• No CMIF as measured by validated instruments for at least 3 months during COT
• Risk from continued treatment outweighs benefit, including decrease in function or concomitant medications
• Severe adverse outcome or overdose event
• Non-compliance with DOH’s pain management rules or AMDG Guideline
• Urine drug tests (UDT) results and/or patient-specific PMP data are aberrant or unexpected
• Drug-seeking, aberrant, or diversion behaviors

How to Taper Opioids

• Start with a taper of ≤10% per week. Rate depends on concurrent treatments or modalities
  ▪ Consider a compulsory taper (2-3 weeks) if the patient does not agree to a voluntary taper or patient with substance use disorder refuse treatment referral
• Prescribe clonidine for withdrawal symptoms such as restlessness, sweating, or tremor
• Use adjunctive therapy during taper or discontinuation (e.g. counseling, psychopharmacological support, SIMP)
• Do NOT reverse taper but it can be slowed. Taper needs to be unidirectional
• Refer patients with opioid use disorder to treatment
When to Access Addiction Treatment

• Assess for opioid use disorder or refer for an assessment if a patient demonstrates aberrant behavior.

• Refer patient to an addiction disorder specialist. If that cannot be done, consult directly with a specialist to identify a treatment plan:
  ▪ Combination of medication and behavioral therapies has been found to be most successful.
  ▪ Medication assisted treatment with either buprenorphine (office-based) or methadone (federally licensed opioid treatment program).
Opioid Use in Special Populations

• Cancer survivors - Model pain treatments after chronic non-cancer pain strategies, rather than palliative therapies

• During pregnancy and neonatal abstinence syndrome - Counsel women on COT to assess potential risk of teratogenicity

• Children and adolescents - Avoid opioids in the vast majority of chronic non-malignant pain problems in children and adolescents

• Older adults -Initiate opioid therapy at a 25% to 50% lower dose than that recommended for younger adults
Concrete State Policy Steps to Take

- Collaboration among state agencies at the highest levels
- Reverse permissive laws
- Set opioid dosing and best practice guidelines/rules for acute, subacute and chronic, non-cancer pain
- Establish metrics for tracking progress; track deaths and overdose ED visits and hospitalizations; track high MED and prescribers
- Implement an effective Rx monitoring program
- Encourage/incent use of best practices (web-based MED calculator, use of state PMPs)
- DO NOT pay for office-dispensed opioids
- ID high prescribers and offer assistance (e.g., academic detailing, free CME, ECHO)
- Incent community-based Rx alternatives (activity coaching and graded exercise early, opioid taper/multidisciplinary Rx later)
  - e.g., cognitive behavioral therapy has been found useful in systematic reviews of at least 8 different chronic pain conditions
Reduce the Development of Preventable Disability

- Decrease the proportion of injured workers on chronic opioids*

<table>
<thead>
<tr>
<th></th>
<th>Baseline: 2012</th>
<th>1Q 2013</th>
<th>2Q 2013</th>
<th>3Q 2013</th>
<th>4Q 2013</th>
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</thead>
<tbody>
<tr>
<td>Percent of claims</td>
<td>4.9%</td>
<td>4.6%</td>
<td>3.3%</td>
<td>1.4%</td>
<td>1.1%</td>
</tr>
<tr>
<td>received with opioids</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6–12 wks from injury</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*2013 opioid guideline for injured workers: [http://1.usa.gov/1nYlarL](http://1.usa.gov/1nYlarL)
What can prescriber do to more safely and effectively use opioids for chronic pain?

- Opioids not first line Rx for most routine conditions
- Use both pharm and non-pharm alternatives

**IF you are using opioids:**

- Opioid treatment agreement
- Screen for prior or current substance abuse/misuse (alcohol, illicit drugs, heavy tobacco use)
- Screen for depression
- Prudent use of random urine drug screening (diversion, non-prescribed drugs)
- Do not use concomitant sedative-hypnotics or benzodiazepines
- Track pain and function to recognize tolerance
- Seek help if morphine equivalent dose (MED) reaches 80 mg/day MED (e.g., Ohio) and pain and function have not substantially improved

- **Use your state Prescription Drug Program to track all sources of controlled substances!**
THANK YOU!

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Questions?