

CDC Guideline for Prescribing Opioids for Chronic Pain

**Clinician Outreach and
Communication Activity
(COCA) Call
June 22, 2016**



Objectives

At the conclusion of this session, the participant will be able to:

- ❑ **Describe what is known about effectiveness and risks of long-term opioid therapy for chronic pain.**
- ❑ **Discuss how to determine when opioids should be initiated or continued for chronic pain, and when they should be discontinued.**
- ❑ **Discuss recommendations for opioid selection and dosage for chronic pain.**
- ❑ **Describe strategies that can be used to assess risk and address harms associated with opioid use.**



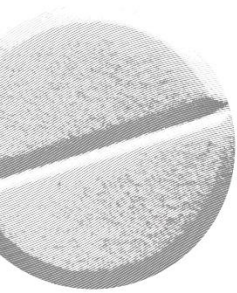
CDC Guideline for Prescribing Opioids for Chronic Pain

Tamara Haegerich, PhD
Deborah Dowell, MD, MPH

June 22, 2016

Chronic Pain and Prescription Opioids

- 11% of Americans experience daily (chronic) pain
- Opioids frequently prescribed for chronic pain
- Primary care providers commonly treat chronic, non-cancer pain
 - account for ~50% of opioid pain medications dispensed
 - report concern about opioids and insufficient training



The amount
of opioids prescribed has
QUADRUPLED
from 1999-2014,



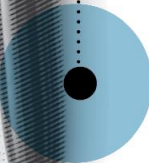
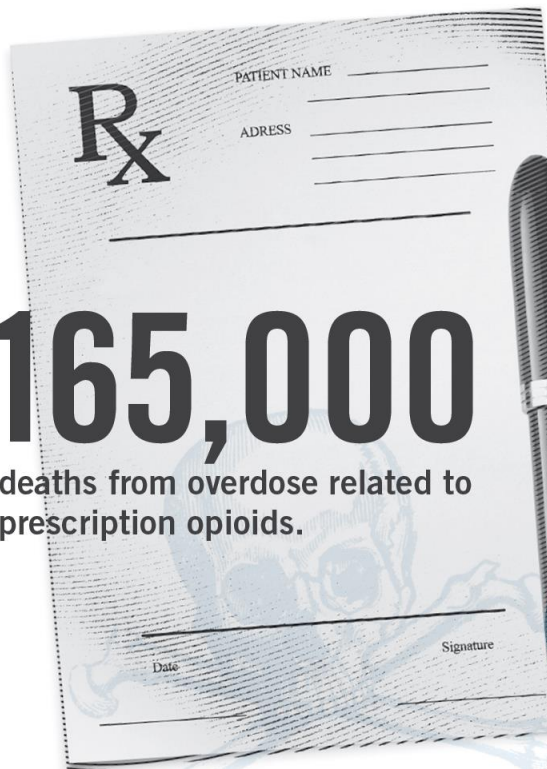
but the pain that
Americans report remains
UNCHANGED



Since 1999, there
have been more than

165,000

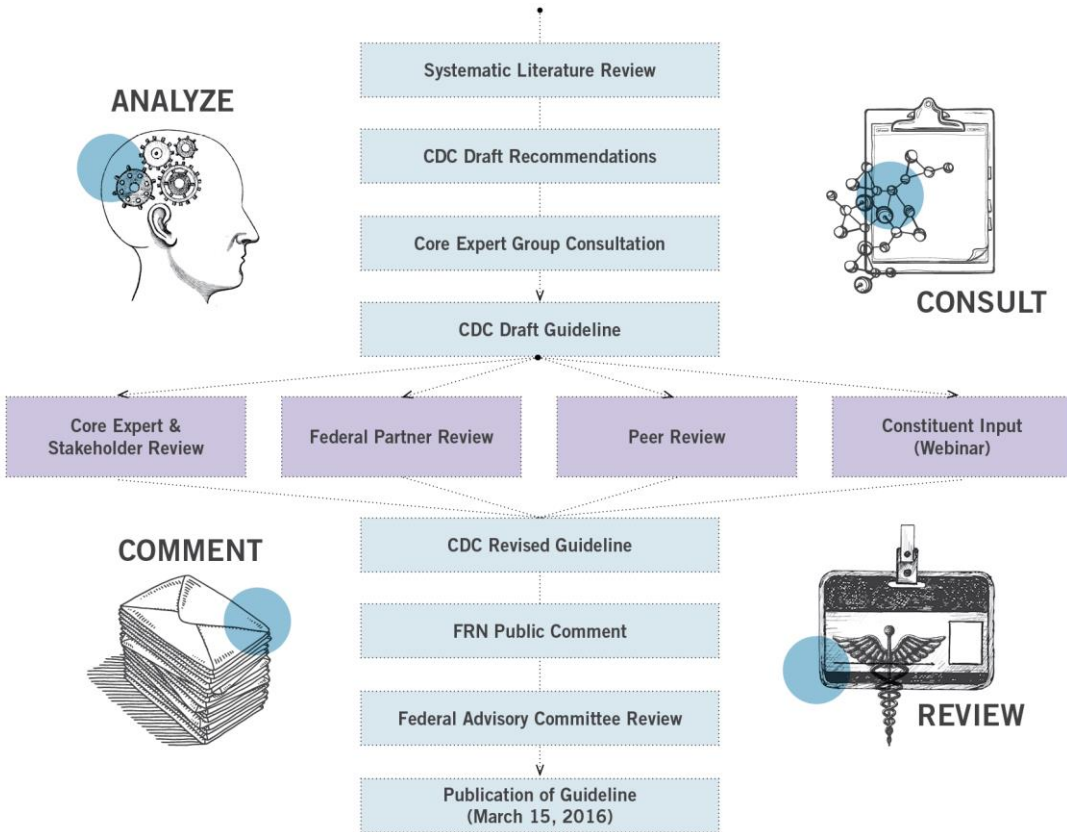
deaths from overdose related to
prescription opioids.



Purpose, Use, and Primary Audience

- Primary Care Providers
 - Family medicine, Internal medicine
 - Physicians, nurse practitioners, physician assistants
- Treating patients ≥ 18 years with chronic pain
 - Pain longer than 3 months or past time of normal tissue healing
- Outpatient settings
- Does not include active cancer treatment, palliative care, and end-of-life care

Guideline Development Process



GRADE Method

- Standard for guideline development
- Transparent approach for conducting systematic review, rating quality of evidence, and determining strength of recommendations
- Used by > 100 organizations
- Recommendations based on:
 - Quality of evidence
 - Balance between benefits and harms
 - Values and preferences
 - Cost

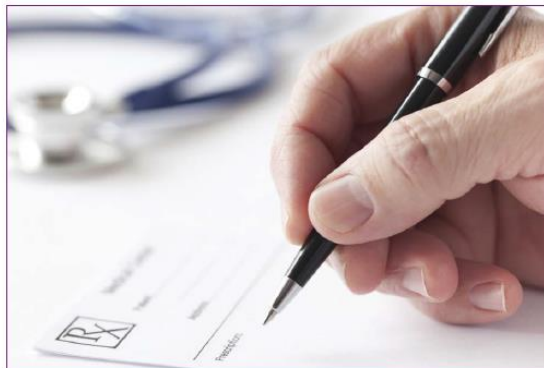
GRADE Evidence Types

- Evidence Types:
 - Type 1: Randomized controlled trials (RCTs); overwhelming observational studies
 - Type 2: RCTs (limitations); strong observational
 - Type 3: RCTs (notable limitations); observational
 - Type 4: RCTs (major limitations); observational (notable limitations) clinical experience

GRADE Recommendation Categories

- Recommendation categories:
 - Category A: applies to all patients; most patients should receive recommended course of action
 - Category B: individual decision making required; providers help patients arrive at decision consistent with values/preferences and clinical situation

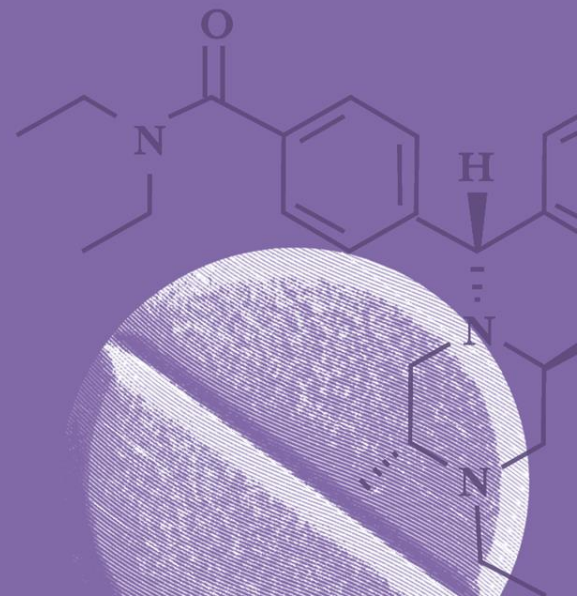
CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016



Continuing Education Examination available at <http://www.cdc.gov/mmwr/cme/conted.html>.



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention



Special Communication

CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016

Deborah Dowell, MD, MPH; Tamara M. Haegerich, PhD; Roger Chou, MD

IMPORTANCE Primary care clinicians find managing chronic pain challenging. Evidence of long-term efficacy of opioids for chronic pain is limited. Opioid use is associated with serious risks, including opioid use disorder and overdose.

OBJECTIVE To provide recommendations about opioid prescribing for primary care clinicians treating adult patients with chronic pain outside of active cancer treatment, palliative care, and end-of-life care.

PROCESSES The Centers for Disease Control and Prevention (CDC) updated a 2014 systematic review on effectiveness and risks of opioids and conducted a supplemental review on benefits and harms, values and preferences, and costs. CDC used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework to assess evidence type and determine the recommendation category.

EVIDENCE SYNTHESIS Evidence consisted of observational studies or randomized clinical trials with notable limitations, characterized as low quality using GRADE methodology. Meta-analysis was not attempted due to the limited number of studies, variability in study designs and clinical heterogeneity, and methodological shortcomings of studies. No study evaluated long-term (>1 year) benefit of opioids for chronic pain. Opioids were associated with increased risks, including opioid use disorder, overdose, and death, with dose-dependent effects.

RECOMMENDATIONS There are 12 recommendations. Of primary importance, nonopioid therapy is preferred for treatment of chronic pain. Opioids should be used only when benefits for pain and function are expected to outweigh risks. Before starting opioids, clinicians should establish treatment goals with patients and consider how opioids will be discontinued if benefits do not outweigh risks. When opioids are used, clinicians should prescribe the lowest effective dosage, carefully reassess benefits and risks when considering increasing dosage to 50 morphine milligram equivalents or more per day, and avoid concurrent opioids and benzodiazepines whenever possible. Clinicians should evaluate benefits and harms of continued opioid therapy with patients every 3 months or more frequently and review prescription drug monitoring program data, when available, for high-risk combinations or dosages. For patients with opioid use disorder, clinicians should offer or arrange evidence-based treatment, such as medication-assisted treatment with buprenorphine or methadone.

CONCLUSIONS AND RELEVANCE The guideline is intended to improve communication about benefits and risks of opioids for chronic pain, improve safety and effectiveness of pain treatment, and reduce risks associated with long-term opioid therapy.

JAMA. doi:10.1001/jama.2016.1664
Published online March 15, 2016.

Editorials

Author Audio Interview at jama.com

Related articles and JAMA Patient Page

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Related articles at jamanetwork.com, jamaopharmacology.com, and jamaneurology.com

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JAMA: The Journal of American Medical Association

Deborah Dowell, Tamara Haegerich, and Roger Chou

CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016

Published online March 15, 2016

JAMA®

The Journal of the American Medical Association

(Screenshot of the CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016)

Clinical Evidence Summary

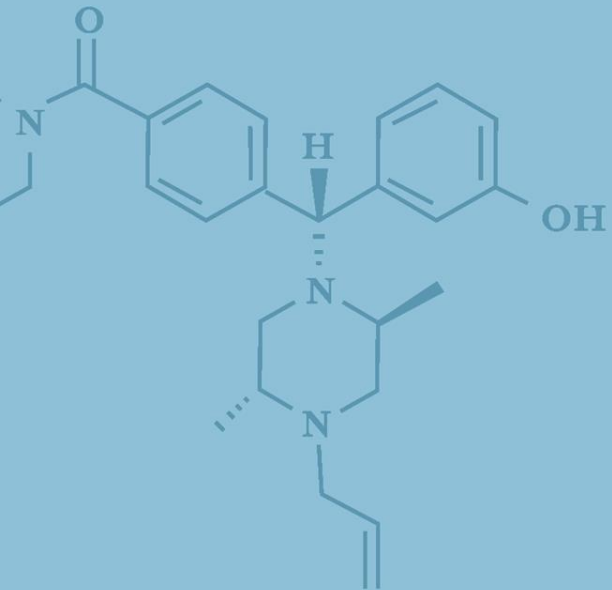
- No long-term (≥ 1 year) outcomes in pain/function; most placebo-controlled trials ≤ 6 weeks
- Opioid dependence in primary care: 3%-26%
- Dose-dependent association with risk of overdose/harms
- Inconsistent results for different dosing protocols; initiation with LA/ER increased risk of overdose
- Methadone associated with higher mortality risk
- No differences in pain/function with dose escalation
- Risk prediction instruments have insufficient accuracy for classification of patients
- Increased likelihood of long-term use when opioids used for acute pain

Contextual Evidence Summary

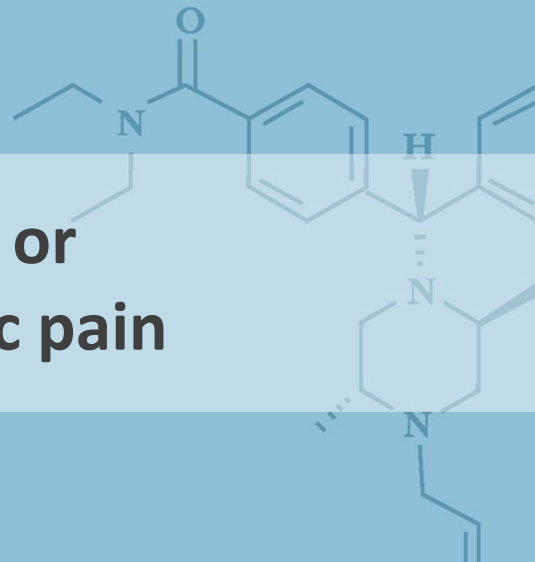
- Effective nonpharmacologic therapies: exercise, cognitive behavioral therapy (CBT), interventional procedures
- Effective nonopioid medications: acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), anticonvulsants, antidepressants
- Opioid-related overdose risk is dose-dependent
- Factors that increase risk for harm: pregnancy, older age, mental health disorder, substance use disorder, sleep-disordered breathing
- Providers lack confidence in ability to prescribe safely and are concerned about opioid use disorder
- Patients are ambivalent about risks/benefits and associate opioids with addiction

Organization of Recommendations

- **The 12 recommendations are grouped into three conceptual areas:**
 - 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



**Determine when to initiate or
continue opioids for chronic pain**



1

Opioids not first-line or routine therapy for chronic pain

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.
- Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient.
- If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

(Recommendation category A: Evidence type: 3)

2

Establish and measure progress toward goals

- Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks.
- Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

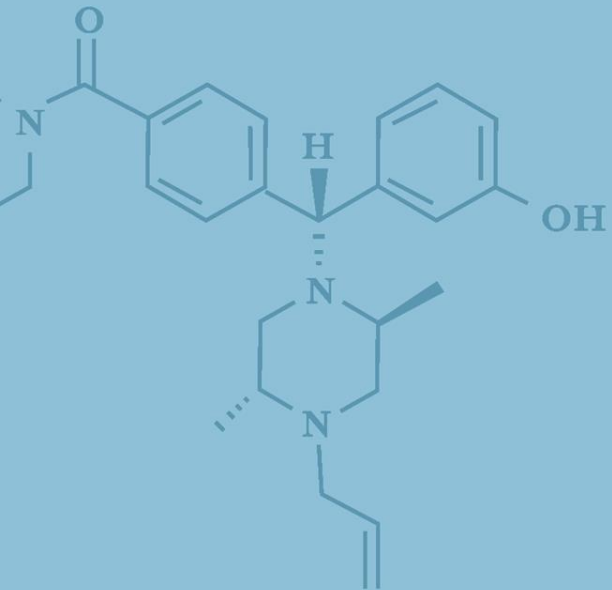
(Recommendation category A: Evidence type: 4)

3

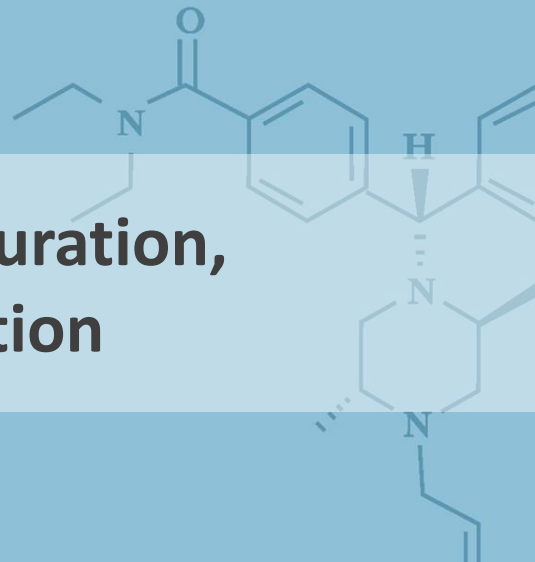
Discuss benefits and risks with patients

- Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

(Recommendation category A: Evidence type: 3)



**Opioid selection, dosage, duration,
follow-up, and discontinuation**



4

Use immediate-release opioids when starting

- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

(Recommendation category A: Evidence type: 4)

Additional cautions for

- *Methadone*
- *Transdermal fentanyl*
- *Immediate-release opioids combined with ER/LA opioids*

5

Use caution at any dose and avoid increasing to high dosages

- When opioids are started, clinicians should prescribe the lowest effective dosage.
- Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day.

(Recommendation category A: Evidence type: 3)

6

Prescribe no more than needed

- Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.
- 3 days or less will often be sufficient; more than 7 days will rarely be needed.

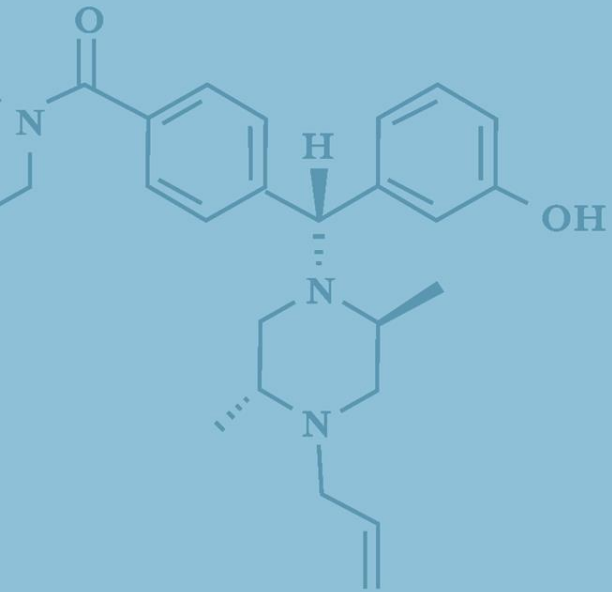
(Recommendation category A: Evidence type: 4)

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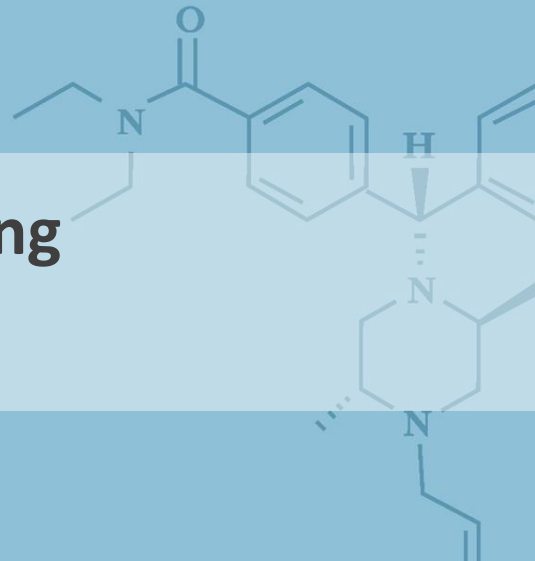
Offer a taper if opioids cause harm or are not helping

- Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation.
- Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.
- If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

(Recommendation category A: Evidence type: 4)



Assessing risk and addressing harms of opioid use



8

Evaluate and address risks for opioid-related harms

- Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms.
- Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use, are present.

(Recommendation category A: Evidence type: 4)

Check PDMP for high dosages and dangerous combinations

- Clinicians should review the patient's history of controlled substance prescriptions using state PDMP data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him/her at high risk for overdose.
- Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

(Recommendation category A: Evidence type: 4)

Test urine for prescribed opioids and other drugs

- When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

(Recommendation category B: Evidence type: 4)

Avoid concurrent opioid and benzodiazepine prescribing

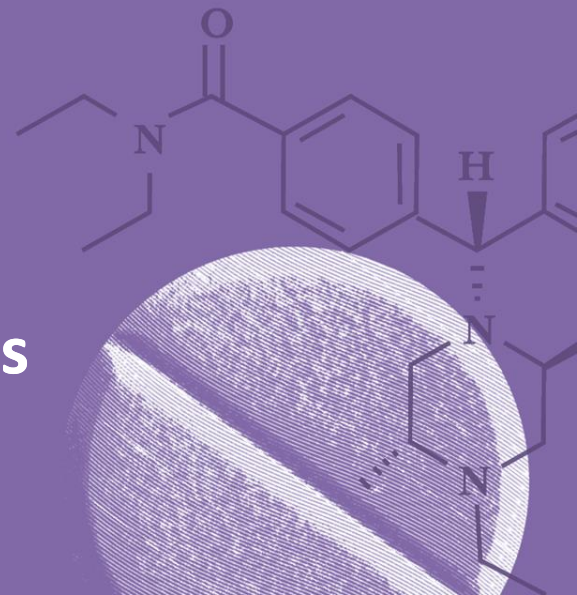
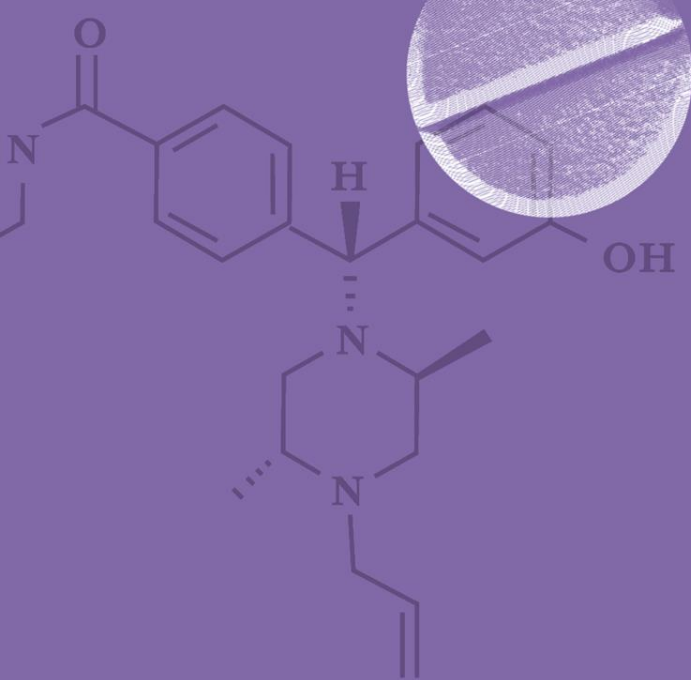
- Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

(Recommendation category A: Evidence type: 3)

Treat patients for opioid use disorder (OUD) if needed

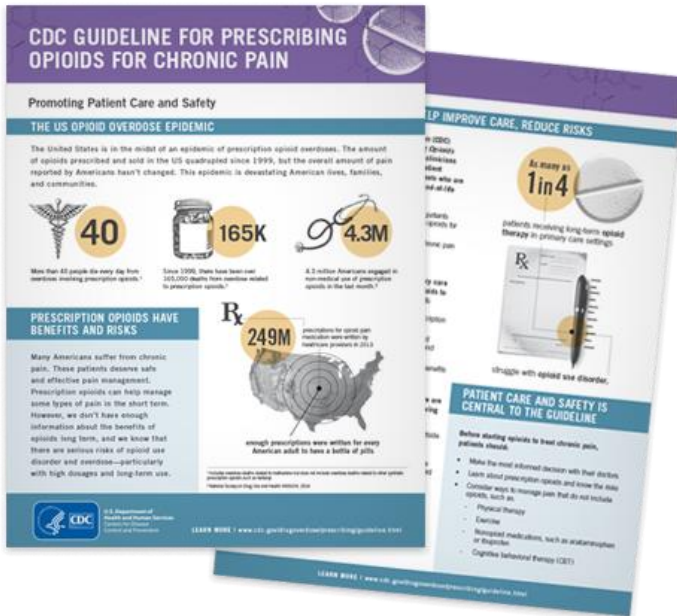
- Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

(Recommendation category A: Evidence type: 2)



Implementation Resources

Resources



- Fact sheets
 - New Opioid Prescribing Guideline
 - Assessing Benefits and Harms of Opioid Therapy
 - Prescription Drug Monitoring Programs
 - Calculating Total Daily Dose of Opioids for Safer Prescribing
 - Pregnancy and Opioid Pain Medications

Checklist for prescribing opioids for chronic pain

Checklist for prescribing opioids for chronic pain

For primary care providers treating adults (18+) with chronic pain ≥ 3 months, excluding cancer, palliative, and end-of-life care

CHECKLIST

When **CONSIDERING** long-term opioid therapy

- Set realistic goals for pain and function based on diagnosis (eg, walk around the block).
- Check that non-opioid therapies tried and optimized.
- Discuss benefits and risks (eg, addiction, overdose) with patient.
- Evaluate risk of harm or misuse.
 - Discuss risk factors with patient.
 - Check prescription drug monitoring program (PDMP) data.
 - Check urine drug screen.
- Set criteria for stopping or continuing opioids.
- Assess baseline pain and function (eg, PEG scale).
- Schedule initial reassessment within 1–4 weeks.
- Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment.

If **RENEWING** without patient visit

- Check that return visit is scheduled ≤ 3 months from last visit.

When **REASSESSING** at return visit

Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.

- Assess pain and function (eg, PEG); compare results to baseline.
- Evaluate risk of harm or misuse:
 - Observe patient for signs of over-sedation or overdose risk.
 - If yes: Taper dose.
 - Check PDMP.
 - Check for opioid use disorder if indicated (eg, difficulty controlling use).
 - If yes: Refer for treatment.
- Check that non-opioid therapies optimized.
- Determine whether to continue, adjust, taper, or stop opioids.
- Calculate opioid dosage morphine milligram equivalent (MME).
 - If ≥ 50 MME/day total (≥ 50 mg hydrocodone; ≥ 33 mg oxycodone), increase frequency of follow up; consider offering naloxone.
 - Avoid ≥ 90 MME/day total (≥ 90 mg hydrocodone; ≥ 60 mg oxycodone), or carefully justify; consider specialist referral.
- Schedule reassessment at regular intervals (≤ 3 months).

REFERENCE

EVIDENCE ABOUT OPIOID THERAPY

- *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.*
- *Short-term benefits small to moderate for pain; inconsistent for function.*
- *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.*

NON-OPIOID THERAPIES

- Use alone or combined with opioids, as indicated:
- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants).
 - Physical treatments (eg, exercise therapy, weight loss).
 - Behavioral treatment (eg, CBT).
 - Procedures (eg, intra-articular corticosteroids).

EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

- Illegal drug use; prescription drug use for nonmedical reasons.
- History of substance use disorder or overdose.
- Mental health conditions (eg, depression, anxiety).
- Sleep-disordered breathing.
- Concurrent benzodiazepine use.

Urine drug testing: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.

Prescription drug monitoring program (PDMP): Check for opioids or benzodiazepines from other sources.

ASSESSING PAIN & FUNCTION USING PEG SCALE

PEG score = average of individual question scores (30% improvement from baseline is clinically meaningful)

- Q1: What number from 0–10 best describes your pain in the past week?**
0 = “no pain”; 10 = “worst you can imagine”
- Q2: What number from 0–10 describes how, during the past week, pain has interfered with your enjoyment of life?**
0 = “not at all”; 10 = “complete interference”
- Q3: What number from 0–10 describes how, during the past week, pain has interfered with your general activity?**
0 = “not at all”; 10 = “complete interference”



U.S. Department of
Health and Human Services
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TO LEARN MORE
www.cdc.gov/drugoverdose/prescribing/guidelines.html

March 2016

(Screenshot of the Checklist for prescribing opioids for chronic pain)

CDC Guideline for Prescribing Opioids
for Chronic Pain

FEASIBILITY for PRIMARY CARE PROVIDERS

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University of Washington, Seattle WA

NIH Pain Consortium
Centers of Excellence in Pain Education



UW Medicine
PAIN MEDICINE

IS IT POSSIBLE TO CHANGE YOUR PRACTICE?

- **Feasible**

- Capable of being done or carried out;
- Capable of being used or dealt with successfully;
- Reasonable
- Likely
 - Merriam Webster Dictionary

- **Imperative**

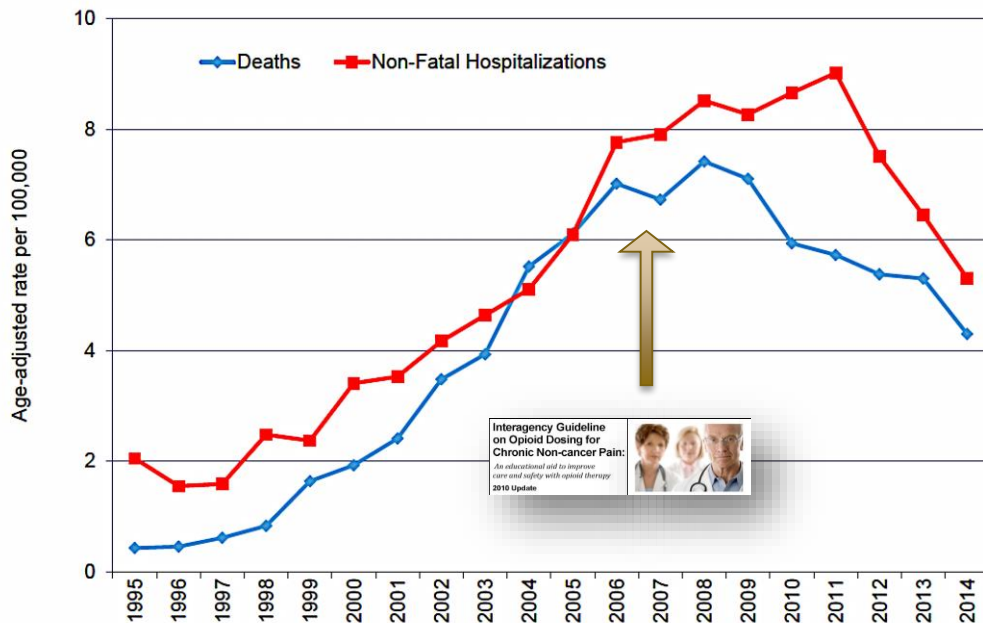
- “Above all, do no harm” – Hippocrates

- **Practical**

- “Vision without execution is hallucination” –Thomas Edison

WASHINGTON STATE'S SUCCESS

Unintentional Prescription Opioid Involved Overdoses Washington State



Source: Jennifer Sabel PhD Epidemiologist, WA State Department of Health, May 2016

- Team approach with pain champion(s)
- Shared clinic policies and assessment tools
 - Consensus for a pain “standard of care”
 - Focus on functional gains
 - Address opioid safety and efficacy
- Emphasis on a multimodal treatment approach
- Address substance use disorders and have referral options with a defined referral process
- Patient self-management classes and support
- Longer visits
- After visit care with Case or Care managers
- Web-based program with Tele-mentoring and E-consults

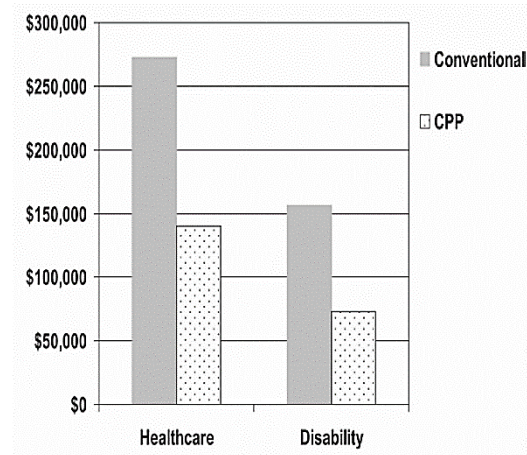
Courtesy of Dr. Melissa Weimer, OHSU

IMPLEMENTING BEST PRACTICES

1. Highstreet Medical Center, Springfield, MA
2. Boston Medical Center's TOPCARE, MA
3. Community Hospital of the Monterey Peninsula, CA
4. Duke University Health System, NC
5. Group Health (Seattle) Learning Health Systems, WA
6. Kaiser Permanente's Southern California Medical Group
7. Lancaster General Health/Penn Medicine, PA
8. Medford Oregon's Opioid Prescribing Group, OR
9. Oregon Health & Science University's PROPEL clinic, OR
10. Priority Health (HMO), Lansing, MI
11. Rhode Island/Miriam Hospitals
12. Temple University Hospital Systems, PA
13. VA/DoD Health systems nationwide: Connecticut, Minneapolis, Indianapolis, Seattle/Puget Sound
14. University of Washington and its UW Neighborhood Clinics

Will you add your clinical practice here: _____?

- Epidemic in America
 - Influenza Pandemic (1918: 500,000)
 - HIV (1981-2005: 550,000)
 - Prescription Opioid ODs (1999-2014: 165,000, and counting)
- Families and communities are suffering from opioid-related accidental deaths and addictions
- Health care expenses can be reduced with multidisciplinary chronic pain care:
 - Reduce direct costs 70%
 - Reduce disability costs 40%



¹Gatchel 2006

HOW?

Guideline Compliant Care

Understand Safe & Effective Chronic Pain Treatments

1. For Clinicians

- CDC Guidelines, & your state's guidelines
- UW's "COPE REMS" www.coperems.org

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

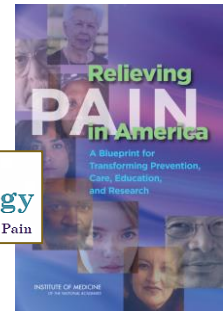


2. For Patients and Families

- YouTube: "Understand Pain", "Brainman Stops His Opioids"
- Stanford's: Chronic Pain Self Management Program
- U. Michigan's: fibroguide.com
- American Chronic Pain Association

3. For Policymakers and Payers

- National Pain Strategy
- IOM 2011 Report: Relieving Pain in America



Step 2: Assess

✓ ***Does your practice:***

- Use registries and regular review based on dose (MME)
- Measure and track function (e.g. PEG) and mood (e.g. PHQ's, GAD, PC-PTSD) when prescribing chronic opioids
- Screen for Misuse/Addiction Risks (e.g. ORT, SOAPP, DIRE)*
- Adhere to monitoring policies and procedures: PDMP, UDT
- Enter Care Agreements & Informed Consent re benefits & harms
- Screen for Medical Risks: e.g. sleep apnea, benzodiazepine use
- Follow protocols for OD high risk/naloxone prescribing
- Have Buprenorphine licensees? And actually prescribe?
- Process for interprofessional referrals? (CBT, PT/OT, Rehab, Addiction)

- **You**, confident of your care provider relational skills, compassion, and capacity to learn and deliver best-practice pain care.
- **Your multidisciplinary/interprofessional pain care team...**
- ...Enabled and enlarged by policies and processes that **your organization's medical and administrative leadership** will need to support.
- Your **patients and families**, since successful chronic pain treatment requires patient engagement and self-management.

*Transformation is a process,
it doesn't happen all at once*

- **Start** with a *sense of urgency*
- **Identify** your team and its champions
- **Engage & communicate** goals within your group and throughout the larger organization
- **Prioritize** internal and external obstacles, and introduce steps that overcome initial barriers
- **Get** quick wins
- **Build** IT and other resources needed to support change
- Regularly **review** and **sustain** processes

SELECTED REFERENCES

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CDC Recommendations for Nonopioid Treatments in the Management of Chronic Pain

**Clinician Outreach and
Communication Activity
(COCA) Call
July 27, 2016**

Objectives

At the conclusion of this session, the participant will be able to:

- ❑ **State the evidence related to effectiveness and potential risks associated with nonopioid treatments for chronic pain.**
- ❑ **Outline nonpharmacologic and nonopioid pharmacologic treatment options for various chronic pain conditions.**
- ❑ **Review patient evaluation methods that can be used to identify the most appropriate treatment options for chronic pain.**
- ❑ **Describe the role of patient beliefs and expectations, and value of exercise, education, and nonopioid drug treatments in the management of musculoskeletal pain complaints.**



CDC Guideline for Prescribing Opioids for Chronic Pain:

Nonopioid Treatments for Chronic Pain

Deborah Dowell, MD, MPH

July 27, 2016

Effectiveness and Harms of nonopioid treatments for chronic pain

Table 3. Effectiveness and Harms of Nonpharmacologic and Nonopioid Pharmacologic Treatments^a

Source	Topic or Intervention	Participants or Population	Primary Outcomes	Key Findings	Study Quality
Busch et al., ²⁰⁰⁷	Exercise training vs untreated control or nonexercise intervention	Systematic review of 33 RCTs with fibromyalgia patients	Global well-being, selected signs and symptoms, and physical capacity	Key finding: Exercise training improves global well-being and physical function. Supervised aerobic exercise training has beneficial effects on physical capacity and fibromyalgia symptoms.	Four studies were classified as high quality, 15 as moderate quality, and 14 as low quality.
Chaparro et al., ²⁰¹⁴	Noninjectable opioids vs placebo or other treatments	Systematic review of 15 RCTs with patients with chronic low back pain	Pain	One trial found tramadol similar to celecoxib for pain relief. Two trials did not find a difference between opioids and antidepressants for pain or function.	Low- to moderate-quality evidence
Collins et al., ²⁰⁰⁰	Antidepressants vs placebo; anticonvulsants vs placebo or diabetic neuropathy or postherpetic neuralgia	Systematic review of 19 RCTs for diabetic neuropathy or postherpetic neuralgia	Pain	For diabetic neuropathy, the NNT for a 50% pain relief was 3.4 for antidepressants (12 trials, 10 evaluated TCAs and 3 SSRIs) and 2.7 for anticonvulsants (3 trials). For postherpetic neuralgia, the NNT was 2.1 for antidepressants (3 studies evaluating TCAs) and 3.2 for anticonvulsants (1 study evaluating gabapentin).	The mean and median quality score for included studies was 4 on a scale of 1-5
Fransen et al., ²⁰¹⁵	Exercise vs nonexercise group (active or no treatment)	Systematic review of 54 RCTs or quasi-randomized trials for knee osteoarthritis	Reduced joint pain or improved physical function and quality of life	Exercise reduced pain, improved function, and improved quality of life immediately after treatment; in studies providing posttreatment follow-up data, improved pain and function were sustained for 2-6 mo.	High-quality evidence for reduced pain and improved quality of life and moderate-quality evidence for improved function
Fransen et al., ²⁰¹⁴	Exercise vs nonexercise group (active or no treatment)	Systematic review of 10 RCTs or quasi-randomized trials for hip osteoarthritis	Reduced joint pain and improved physical function and quality of life	Exercise reduced pain and improved function immediately after treatment; in studies providing posttreatment follow-up data, improved pain and function were sustained for at least 3-6 mo.	High-quality evidence for reduced pain and improved function
Häuser et al., ²⁰¹³	Duloxetine vs placebo; milnacipran vs placebo	Systematic review of 10 RCTs for fibromyalgia patients	Benefits and harms	Duloxetine and milnacipran reduced pain by a small amount compared with placebo.	Risk of bias in included studies was low
Hayden et al., ²⁰⁰⁵	Exercise therapy vs no treatment, other conservative treatments	Systematic review consisting of 61 RCTs for low back pain	Pain, function	Exercise therapy reduces pain and improves function with small magnitudes of effect. Effectiveness of exercise therapy appears to be greater in populations visiting a health care provider compared with the general population.	Only a small number of studies rated as high quality; potential publication bias
Lee et al., ²⁰¹⁴	CIM therapies vs single self-care CIM, non-self-care CIM, usual care/no treatment, other multimodal program, or other control	Systematic review of 26 RCTs for management of chronic pain	Pain symptoms	Integrative multimodal therapies resulted in positive, but sometimes mixed, effects on pain symptoms compared with active controls or single self-care modalities. More studies are needed to make strong conclusions about effectiveness.	Large majority of poor quality, including weaknesses in randomization and allocation and concealment
Lunn et al., ²⁰¹⁴	Duloxetine vs placebo or other controls	Systematic review of 18 RCTs for neuropathic pain, chronic pain conditions without identified cause, or fibromyalgia	Benefits and harms of duloxetine	Duloxetine at 60 mg and 120 mg daily, but not lower dosages, were effective in reducing pain in diabetic peripheral neuropathy pain and in fibromyalgia.	Moderate-quality evidence for diabetic neuropathy and lower-quality evidence for fibromyalgia; some risk of bias
Moore et al., ²⁰⁰⁹	Pregabalin vs placebo or any active control	Systematic review of 25 double-blind RCTs for postherpetic neuralgia, painful diabetic neuropathy, central neuropathic pain, or fibromyalgia	Analgesic efficacy and associated adverse events	Pregabalin was effective in patients with postherpetic neuralgia, diabetic neuropathy, central neuropathic pain, and fibromyalgia at doses of 300 mg, 450 mg, and 600 mg (but not at 150 mg) daily. NNTs were generally <6 for moderate benefit in postherpetic neuralgia and diabetic neuropathy but <7 for fibromyalgia.	Studies all had Oxford quality scores based on randomization, blinding, and reporting of dropout <2 (out of maximum of 5)
Moore et al., ²⁰¹⁴	Gabapentin vs placebo	Systematic review of 37 RCTs for neuropathic pain or fibromyalgia	Analgesic efficacy and adverse effects	Gabapentin was significantly more effective than placebo in reducing pain in diabetic neuropathy and postherpetic neuralgia. Evidence was insufficient for other conditions.	"Second-tier" evidence (some risk of bias, but adequate numbers in the trials)

(continued)

The full table of reviews of non-opioid therapies is available in JAMA's publication of CDC's Guideline for Prescribing Opioids for Chronic Pain - United States, 2016.



Overview of findings from the evidence reviews

- Insufficient evidence to determine whether pain relief, function, or quality of life improves with long-term opioid therapy (most RCTs <6 weeks)
- Long-term opioid use for chronic pain is associated with serious risks, including abuse, dependence and overdose
- Many non-opioid therapies can improve chronic pain with less risk for harm
- When opioids are used, they are more likely to be effective if combined with other approaches

1

Opioids not first-line or routine therapy for chronic pain

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.
- Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient.
- If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

(Recommendation category A: Evidence type: 3)

Effective treatments for chronic pain

- Nonpharmacologic therapies
 - Exercise therapy
 - Cognitive-behavioral therapy
- Nonopioid pharmacologic treatments
 - Acetaminophen
 - NSAIDs, and COX-2 inhibitors
 - Selected anticonvulsants (e.g., pregabalin, gabapentin)
 - Selected antidepressants (tricyclics, SNRIs)
- Interventional approaches
- Multimodal and multidisciplinary therapies

Nonpharmacologic therapies can

- Result in sustained improvements in pain and function without apparent risks
- Encourage active patient participation in the care plan
- Address the effects of pain in the patient's life

Exercise therapy

- High-quality evidence for reduced pain and improved function for hip or knee osteoarthritis
 - Immediately after treatment
 - Improvements sustained for at least 2–6 months
- Previous guidelines strongly recommended aerobic, aquatic, and/or resistance exercises for patients with hip or knee osteoarthritis
- Can reduce pain and improve function in low back pain
- Can improve global well-being, fibromyalgia symptoms, and physical function in fibromyalgia

Cognitive behavioral therapy (CBT)

- Addresses psychosocial contributors to pain and improves function
- Trains patients in behavioral techniques
- Helps patients modify situational factors and cognitive processes that exacerbate pain
- Has small positive effects on disability and catastrophic thinking

Access to nonpharmacologic treatments

- Access and cost can be barriers
- Aspects of these approaches can be used even when there is limited access to specialty care
 - RCT: no difference in reduced chronic low back pain intensity, frequency or disability between
 - Patients assigned to relatively low-cost group aerobics
 - Individual physiotherapy sessions
 - Low-cost options to integrate exercise:
 - Brisk walking in public spaces
 - Use of public recreation facilities for group exercise

Using CBT principles in primary care

- Encourage patients to take an active role
- Teach relaxation techniques
- Support engaging in beneficial but potentially anxiety-provoking activities, such as exercise
- Support patient coping strategies
- Refer patients to support, self-help, and educational community-based programs
- Refer patients with more entrenched anxiety or fear related to pain, or other significant psychological distress, for formal therapy with a mental health specialist

Acetaminophen

- Multiple guidelines: acetaminophen first-line for
 - Osteoarthritis
 - Low back pain
- Can be hepatotoxic at > 3-4 grams/day and at lower dosages in patients with chronic alcohol use or liver disease
 - Avoid in liver failure
 - Reduce dosage in patients with
 - Hepatic insufficiency
 - History of alcohol abuse

NSAIDs and cyclooxygenase 2 (COX-2) inhibitors

- NSAIDs first-line treatment for
 - Osteoarthritis
 - Low back pain
- NSAIDs and COX-2 inhibitor risks:
 - Gastritis, gastrointestinal bleeding or perforation
 - Fluid retention, renal and cardiovascular risks
 - Interference with platelet aggregation
 - Topical NSAIDs have less systemic risk than oral NSAIDs

Selected antidepressants

- Tricyclics (TCAs, e.g., amitriptyline) and SNRIs (e.g., duloxetine) are effective and recommended in multiple guidelines for
 - Neuropathic pain (e.g., diabetic neuropathy, post-herpetic neuralgia)
 - Fibromyalgia symptoms
- TCAs relatively contraindicated in severe cardiac disease, particularly conduction disturbances
- Start TCAs at low dosages, titrate up as needed and tolerated
 - Often effective at lower dosages than for depression
 - Anticholinergic effects include sedation--use at bedtime

Selected anticonvulsants

- Selected anticonvulsants (e.g., pregabalin, gabapentin) are effective and recommended in multiple guidelines for
 - Neuropathic pain (e.g., diabetic neuropathy, post-herpetic neuralgia)
 - Fibromyalgia symptoms
- Start pregabalin or gabapentin at low dose and increase gradually given dose-dependent dizziness and sedation
- Check baseline and periodic CBC and LFTs with carbamazepine

Interventional approaches

- Injections can improve short-term pain and function
 - Arthrocentesis and intraarticular glucocorticoid injection in rheumatoid arthritis or osteoarthritis
 - Subacromial corticosteroid injection in rotator cuff disease
 - Epidural injection for lumbar radiculopathy
- Potential risks
 - Articular cartilage changes (in osteoarthritis)
 - Sepsis
 - Rare but serious adverse events associated with epidural injection: loss of vision, stroke, paralysis, death

Multimodal and multidisciplinary therapies

- Can reduce long-term pain and disability more effectively than single modalities
- Involve coordination of medical, psychological, and social aspects of care
- Are not always available or reimbursed by insurance
- Can be time-consuming and costly for patients
- Should be considered for patients not responding to single-modality therapy, or who have severe functional deficits
- Combinations should be tailored depending on patient needs, cost, and convenience

Selection of therapy: evaluation

- Evaluate patients, establish or confirm diagnosis
 - Focused history, including
 - History and characteristics of pain
 - Contributing factors (psychosocial stressors, sleep)
 - Physical exam
 - Imaging *only if indicated*, e.g., if
 - Severe or progressive neurologic deficits are present or
 - Serious underlying conditions are suspected
- For complex pain syndromes, consider pain specialty consultation to assist with diagnosis as well as management

Selection of therapy: role of pain mechanism and diagnosis

- NSAIDs for nociceptive pain (e.g., osteoarthritis, muscular back pain)
- Selected antidepressants or anticonvulsants for neuropathic pain (e.g., diabetic neuropathy, postherpetic neuralgia) or fibromyalgia); topical lidocaine for localized neuropathic pain
- Physical or occupational therapy can address posture, weakness, or repetitive motions contributing to musculoskeletal pain
- Surgical intervention can relieve mechanical/compressive pain
- Glucose control can prevent progression of diabetic neuropathy
- Immune-modulating agents useful in rheumatoid arthritis

Selection of therapy: role of risk factors for harm

- Use medications only after determining expected benefits outweigh risks given patient-specific factors
- Consider falls risk when selecting and dosing potentially sedating medications (e.g., tricyclics, anticonvulsants, opioids)
- Weigh risks and benefits of use, dose, and duration of NSAIDs when treating older adults, patients with hypertension, renal insufficiency, or heart failure, or those at risk for peptic ulcer disease or cardiovascular disease
- Consider topical NSAIDs over oral NSAIDs for localized osteoarthritis (e.g., knee osteoarthritis) in patients aged ≥ 75

CDC Guideline for Prescribing Opioids
for Chronic Pain

NON-OPIOID MEDICATIONS & NONPHARMACOLOGIC TREATMENT

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UW Medicine
PAIN MEDICINE

CASE LEARNING OBJECTIVES

1. Outline the differential diagnoses for this patient's symptoms, and the methods to choose among them.
2. Identify patient belief systems that might interfere with treatment, and strategies to address these.
3. Review the role of patient education in setting expectations when managing musculoskeletal pain.
4. Describe the rationale for exercise therapy, and how to overcome patient barriers to physical therapy.
5. Defend the rationale for use of a tricyclic antidepressant drug as the initial medication for this patient.

PATIENT HISTORY – 7/8/14

- Gender: Male
- Age: 38
- Symptoms
 - Non-radicular, aching, stabbing neck pain x 3 weeks
 - Intermittent neck pain/headaches starting in 2008. Also: headaches, diffuse bilateral upper extremity pain + thoracic & lumbar spine
- Electromyography (EMG) 6 years ago: normal
- Magnetic resonance image (MRI) 3 weeks ago:
 - Degenerative disc disease (DDD) + foraminal narrowing C5-6; C6-7

HISTORY CONTINUED

- Rx: oxycodone 5/325 twice daily; cyclobenzaprine 10 mg at bedtime
- Mood: “grumpy because of pain”
- Past medical history: Irritable Bowel Syndrome
- Smokes ½ packs per day; no illicit drugs
- Lives with girlfriend + 10 y/o daughter
- Job: builds cranes; can’t make it to work one day per week
- Activity: 3 hours in recliner after work

PATIENT REPORTED OUTCOME MEASURES

- **Pain, interference with Enjoyment, General function (PEG) tool**
 - ± Brief Pain Inventory (BPI)
 - ± Promise 10
 - ± Oswestry Disability Index (ODI)
 - ± Roland Morris Disability Questionnaire (RMDQ)
- **Personal Health Questionnaire PHQ-9 + General Anxiety Disorder GAD-7**
 - Or short version PHQ-4
 - When elevated ↑ : full PHQ-9, GAD-7 plus Primary Care-Post Traumatic Stress Disorder PC-PTSD
- **Alcohol Use Disorders Identification Test AUDIT-C**
- **ORT, SOAPP, COMM, or DIRE**
 - All of these misuse/addiction tools are widely used, though poor predictive validity
- **Prescription Drug Monitoring Program (PDMP)**
 - Important to check, he may request an opioid refill!

CDC RECOMMENDED ASSESSMENTS

Pain average, interference with
Enjoyment of life, and interference
with General activity
(PEG) Assessment Scale

1. What number best describes your pain on average in the past week:

0 1 2 3 4 5 6 7 8 9 10

No pain Pain as bad as
you can imagine

2. What number best describes how, during the past week, pain has interfered with your enjoyment of life?

0 1 2 3 4 5 6 7 8 9 10

Does not interfere Completely
interferes

3. What number best describes how, during the past week, pain has interfered with your general activity?

0 1 2 3 4 5 6 7 8 9 10

Does not interfere Completely
interferes

Patient Health
Questionnaire PHQ-4

- Combines Generalized Anxiety Disorder GAD-7 + PHQ-9
- Score ≥ 6 needs attention

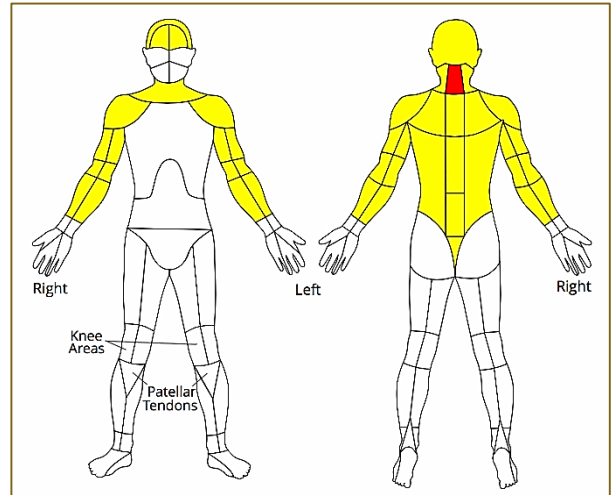
Over the past 2 weeks have you been bothered by these problems?	Not at all	Several days	More days than not	Nearly every day
Feeling nervous, anxious, or on edge	0	1	2	3
Not being able to stop or control worrying	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3
Little interest or pleasure in doing things	0	1	2	3

(Screenshots of the PEG Assessment Scale and PHQ-4)

Krebs 2009, Kroenke 2009

PATIENT REPORTED OUTCOMES (PROs)

- Pain intensity: 6/10
- Pain interference with:
 - General function: 7/10
 - Quality of life: 7/10
 - Sleep:
 - Initiation: 6
 - Maintenance: 6
- Mood: PHQ-4: 6/12
 - ...so added, GAD-7: 6/21
 - ...and, PHQ-9: 8/27



Patient self-selected important activity ("work"): 8

Oswestry Disability Index: 50

Opioid Risk Tool: 4

Satisfaction with pain treatment:
2/10

EXAM

- Height: 5'7" and Weight:119 lbs
 - Normal = 130 lbs; Body mass index (BMI) 18.6
- Vital Signs normal
- 14/18 “tender points”
- Limited range of motion – neck, lumbar
- Neuro –
 - Normal deep tendon reflexes (DTRs)
 - No long tract signs
 - Pain inhibited weakness both upper extremities (UEs)
 - Sensation normal

MAKE MULTIDIMENSIONAL ASSESSMENT

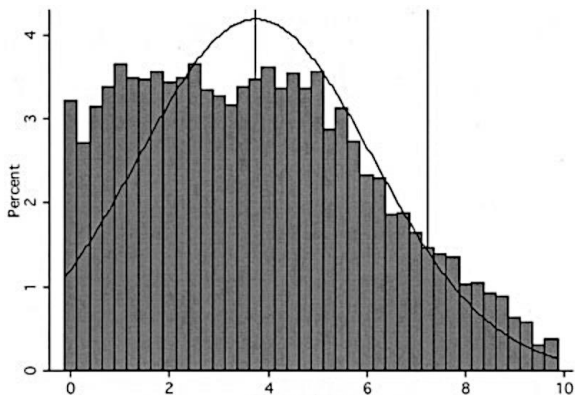
Diagnoses

1. Axial neck pain (“cervicalgia”)
2. Fibromyalgia vs. inflammatory arthritis
3. Weight loss, unexplained
4. Long-term opioid therapy, low dose
5. Irritable bowel syndrome
6. Mild depression and anxiety
7. Moderate sleep disturbance

WIDESPREAD PAIN & CO-OCCURRING PAIN DISORDERS

“Fibromyalgia-ness”

Symptom Intensity Scale



Widespread Pain Index
(1 point per check box; score range: 0-19 points)

① Please indicate if you have had pain or tenderness during the past 7 days in the areas shown below. Check the boxes in the diagram for each area in which you have had pain or tenderness.

Symptom Severity
(score range: 0-12 points)

② For each symptom listed below, use the following scale to indicate the severity of the symptom during the past 7 days.

- No problem
- Slight or mild problem: generally mild or intermittent
- Moderate problem: considerable problems; often present and/or at a moderate level
- Severe problem: continuous, life-disturbing problems

	No problem	Slight or mild problem	Moderate problem	Severe problem
Points	0	1	2	3
A. Fatigue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B. Trouble thinking or remembering	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C. Waking up tired (unrefreshed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

③ During the past 6 months have you had any of the following symptoms?

Points	0	1
A. Pain or cramps in lower abdomen	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
B. Depression	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
C. Headache	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes

Additional criteria (no score)

④ Have the symptoms in questions 2 and 3 and widespread pain been present at a similar level for at least 3 months?

No Yes

⑤ Do you have a disorder that would otherwise explain the pain?

No Yes

- As patients move up the Symptom Intensity Scale, they meet the criteria for fibromyalgia
- Currently popular Widespread Pain Index allows patients to locate and describe pain

Clauw 2014, Wolfe 2009

ESTABLISH TREATMENT PLAN

Plan

1. Discuss likely diagnoses and treatment plan
2. Set up appropriate expectations
 - Records from current health care provider(s)
 - Intentions and plans regarding long-term opioids
3. Labs
 - C-reactive protein (CRP)
 - Anti-cyclic citrullinated peptide antibody (anti-CCP)
 - Anti-nuclear antibody (ANA)
4. Visit summary with links to info on Fibromyalgia
(e.g. fibroguide.com)

FOLLOW UP – 7/22/14

- Resists diagnosis of Fibromyalgia
 - ...“it is a ‘psychological’ condition”
- Continue discussion of Fibromyalgia pathophysiology
 - Offer brief education re pain mechanisms and treatment to help understand pain
 - Suggest educational materials
- Referral to physical therapy (PT) for neck range of motion (ROM)/strength + general conditioning

EXERCISE – GENERAL POINTS

1. Exercise is good; PT is a means

“Closest thing to a wonder drug? Try exercise”

2. Optimal exercise? No definite evidence

3. PT/exercise often “fails”

“...made my pain worse!”

4. Clinician interventions

- Find PT who will work with complex pts
- Ask about progress – have pt demonstrate
- Basic concepts – baseline; “exchange list”; tolerance for flares

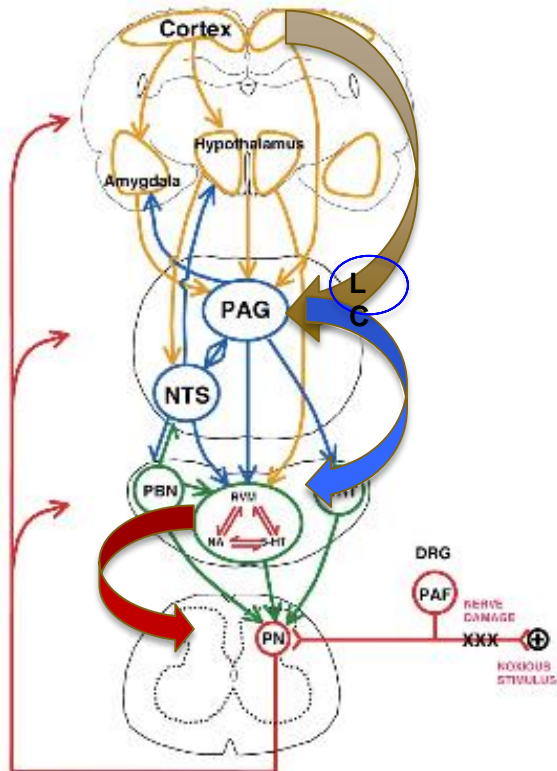
Carroll 2016, Hayden 2005

FOLLOW UP – 7/22/14 (2)

- Discontinue cyclobenzaprine, in favor of **nortriptyline** 10 mg
 - Slow managed titration to 50 mg qhs
- Off opioids because previous prescriber no longer in local practice
 - Consider periodic checking PDMP regardless

WHY NORTRIPTYLINE?

DESCENDING INHIBITORY CONTROL SYSTEMS



Norepinephrine is a principal neurotransmitter facilitating the “descending inhibitory systems”.

The diagram shows how nortriptyline works by inhibiting norepinephrine reuptake.

Millan 2002, Ossipov 2014

CLINICAL TRIALS FOR TCA EFFECTIVENESS:

Post Herpetic Neuralgia

NNT* 2.1-2.7

Diabetic Peripheral Neuropathy

NNT* 1.2-1.5

Atypical Facial Pain

NNT* 2.8-3.4

Fibromyalgia/Central Pain

NNT* 1.7

*NNT = Number needed to treat

Saarto 2007

FOLLOW UP, OVER MONTHS

8/27/14

1. Nortriptyline + PT – reduction in widespread pain
2. Neck pain/headaches still present, but less
 - Pain reduced 10%
 - Rest of PEG improved 40%
 - PHQ-4 = 4
3. Sleep better
4. Exam – reduced sensitivity of tender points

9/25/14

1. Nortriptyline – AM fatigue, some dry mouth
2. Pain still 6/10
3. Rest of PEG improved 60% from baseline
4. PHQ-4 = 2

NON-DRUG MULTIMODAL ANALGESIA

- **Cognitive:**
 - Identify distressing negative cognitions and beliefs
- **Behavioral approaches:**
 - Mindfulness, relaxation, biofeedback
- **Physical:**
 - Activity coaching, graded exercise land & aquatic with PT, class, trainer, and/or solo
- **Spiritual:**
 - Identify and seek meaningfulness and purpose of one's life
- **Education (patient and family):**
 - Promote patient efforts aimed at increased functional capabilities

“COMPARING” EFFECTIVENESS*

PAIN TREATMENTS	EXTRAPOLATED BENEFITS FOR VARIED PAIN OUTCOMES
Opioids	≤ 30%
Tricyclics/SNRIs	30%
Anticonvulsants	30%
Acupuncture	≥ 10%
Cannabis	10-30%
CBT/Mindfulness	15-50%
Graded Exercise Therapy	variable
Sleep Restoration	≥ 40%
Hypnosis, Manipulation, Yoga	“+ effect”

*NOTE

- *Many studies low GRADE quality of evidence*
- *Most studies <3 months*
- *Rarely do studies compare one treatment with another*

See also: CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. 2016;315(15):1624-1645.

FOLLOW UP

11/5/14

1. Recent flare up of neck pain
2. Reviewed PT exercises – mainly stretching
3. Discuss neck/shoulder girdle strengthening
4. Sleep/fatigue – trazodone vs. more nortriptyline

2/10/15

1. Weight = 140 (BMI 22)
2. Sleep improved – nortriptyline, amitriptyline, trazodone
3. Worse UE sx's; possible C6 radic – work up?

SUMMARY

- Anticipate multiple symptoms
- Prepare for adversity
- Setting expectations is key
- Continuing re-evaluation
- Always consider psychosocial factors

Pain management takes time – many dimensions that evolve over time

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Assessing Benefits and Harms of Opioid Therapy for Chronic Pain

Clinician Outreach and
Communication Activity
(COCA) Call
August 3, 2016

Objectives

At the conclusion of this session, the participant will be able to:

- ❑ Describe the evidence for the benefits and harms of opioid therapy for chronic pain outside of active cancer treatment, palliative, and end-of-life care.
- ❑ Review methods for setting goals for pain management with patients.
- ❑ Summarize factors that increase risk for harm and how to assess for such factors.
- ❑ Review methods for assessing patients' pain and function, and for conducting appropriate follow-up.



CDC Guideline for Prescribing Opioids for Chronic Pain: Assessing Benefits and Harms of Opioid Therapy

Deborah Dowell, MD, MPH

August 3, 2016

Difficult to predict benefits and harms of long-term opioid use in individual patients

- Unclear whether there are long-term benefits
- Short-term benefits
 - Small to moderate for pain
 - Inconsistent for function
- Serious risks include opioid use disorder and overdose
- Risk assessment instruments do not consistently predict opioid abuse or misuse

1

Opioids not first-line or routine therapy for chronic pain

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.
- Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient.
- If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

(Recommendation category: A; Evidence type: 3)

2

Establish and measure progress toward goals

- Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks.
- Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

(Recommendation category: A; Evidence type: 4)

Before starting long-term opioids for chronic pain

1. Determine whether expected benefits for both pain and function are anticipated to outweigh risks to the patient
2. Establish treatment goals*
3. Set criteria for stopping or continuing opioids
4. Have an “exit strategy” for discontinuing therapy

*For patients already receiving opioids, establish goals for continued treatment

Assessing likely benefits of opioid therapy for individual patients

- Consider diagnosis (insufficient evidence for long-term benefits in headache, fibromyalgia, nonspecific back pain)
- Consider patient goals
 - Opioids might reduce pain in the short term
 - Opioids might reduce intermittent exacerbations of pain
 - Opioids might not reduce pain effectively long term
 - Opioids unlikely to eliminate pain
 - No demonstrated long-term improvement in function

8

Evaluate and address risks for opioid-related harms

- Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms.
- Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use, are present.

(Recommendation category: A; Evidence type: 4)

Assessing for mental health conditions

- Treatment for depression may decrease overdose risk when opioids are used
- Assess for anxiety, PTSD, and depression using validated tools, e.g.,
 - Generalized Anxiety Disorder (GAD)-7
 - Patient Health Questionnaire (PHQ)-9
 - PHQ-4

Assessing for substance use disorder

- Ask patients about their drug and alcohol use
 - Single screening questions can be used, e.g., “How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?”
 - Validated screening tools can also be used, e.g.,
 - Drug Abuse Screening Test (DAST)
 - Alcohol Use Disorders Identification Test (AUDIT)
- Use PDMP data and urine drug testing to assess for concurrent substance use

Establishing treatment goals

- Include goals for both pain and function
 - Improvement in physical function not always realistic (e.g., catastrophic spinal injury)
 - Function can include emotional and social dimensions
- Set realistic, meaningful functional goals (e.g., walk around block)
- Set goals for objective improvement
- Use validated instruments such as the PEG* Assessment Scale
 - Clinically meaningful improvement: $\geq 30\%$ improvement

* Pain average, interference with Enjoyment of life, and interference with General activity (PEG) Assessment Scale

3-item (PEG) Assessment Scale

- 1. What number best describes your pain on average in the past week?** (from 0=no pain to 10=pain as bad as you can imagine)
- 2. What number best describes how, during the past week, pain has interfered with your enjoyment of life?** (from 0=does not interfere to 10=completely interferes)
- 3. What number best describes how, during the past week, pain has interfered with your general activity?** (from 0=does not interfere to 10=completely interferes)

PEG = Pain average, interference with Enjoyment of life,
and interference with General activity

7

Re-evaluate benefits and harms of opioids, and continue therapy only as a deliberate decision

- Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation.
- Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.
- If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

(Recommendation category: A; Evidence type: 4)

How often to evaluate patients to assess benefits and harms of long-term opioid use?

- Within 1 - 4 weeks of starting or increasing dosage
 - Within 1 week when
 - Starting or increasing ER/LA opioids
 - Total daily opioid dosage ≥ 50 MME/day
 - Within 3 days when starting or increasing methadone
- Regularly reassess at least every 3 months
- Reassess patients exposed to greater risk more frequently
 - Depression or other mental health conditions
 - History of substance use disorder or overdose
 - Taking ≥ 50 MME/day or other CNS depressants

Before continuing long-term opioids for chronic pain, ask

- Do opioids continue to meet treatment goals?
 - Progress toward individual patient goals?
 - Sustained, meaningful improvement in pain and function?
- Are there adverse events or early warning signs?
 - Over-sedation or overdose risk (if yes, taper dose)
 - Signs of opioid use disorder (if yes, treat or refer)
- Do benefits continue to outweigh risks?
- Can dosage can be reduced?
- Can opioids can be discontinued?

CDC Guideline for Prescribing Opioids

ASSESSING BENEFITS AND HARMS OF OPIOID THERAPY

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CASE: 46 YR OLD WOMAN WITH FM

- Ms. Christie is a 46 year old woman who has had fibromyalgia for the past three years. She was sent by her primary care provider to a rheumatologist who diagnosed fibromyalgia after a physical exam and an extensive series of blood tests.
- Her primary care provider treated her with gabapentin 300mg qAM and 600mg qHS with moderately good results. She continued to have moderate 5/10 pain, but she was able to continue her job as a receptionist and her role as wife and mother to two high-school students.

1

Opioids not first-line or routine therapy for chronic pain

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.
- Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient.
- If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

(Recommendation category: A; Evidence type: 3)

NATIONAL INSTITUTES OF HEALTH PATHWAYS TO PREVENTION WORKSHOP

- “Evidence is insufficient to determine the effectiveness of long-term opioid therapy for improving chronic pain and function. Evidence supports a dose-dependent risk for serious harms.”
- Chou R et al *Annals Intern Med* 2015; 162:276-86

OPIOID TREATMENT OF FIBROMYALGIA

- Opioid analgesics are commonly used for the treatment of fibromyalgia (FM) despite multiple treatment guidelines that recommend against the use of long-term opioid therapy
 - American Pain Society and the American Academy of Pain Medicine
 - American Academy of Neurology
 - European League Against Rheumatism
 - Canadian Pain Society and the Canadian Rheumatology Association
 - British Pain Society

OPIOID TREATMENT OF FIBROMYALGIA

- Cochrane 2014 review concludes there is “no evidence at all” of oxycodone efficacy for fibromyalgia
- Tramadol may be effective in the treatment of FM but it is a weak opioid receptor agonist, and its efficacy in FM is likely related to its action as a serotonin-norepinephrine reuptake inhibitor.

CASE: 46 YEAR OLD WOMAN WITH FM

- Three months before today's visit, Ms. Christie was rear-ended when stopped at a stoplight. She suffered a significant exacerbation of her fibromyalgia. She reported severe 8/10 pain in the ED immediately after the crash. She had no fractures, but was diagnosed with neck and back sprain. At that time she was prescribed oxycodone 5mg every 4 hours as needed for pain.
- She continued to complain of severe 7/10 widespread pain despite taking 20mg oxycodone when she saw her primary care provider 2 weeks after the crash. Furthermore, she said that she was no longer able to do her job or fulfill her responsibilities at home.

2

Establish and measure progress toward goals

- Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks.
- Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

(Recommendation category: A; Evidence type: 4)

CASE: 46 YR OLD WOMAN WITH FM

She asked her primary care provider to increase her oxycodone dose to improve her pain and function level. Her primary care provider wanted to help her keep her job, so he wrote for oxycodone ER 20mg twice a day. When he checked in with her a week later, she reported feeling better and was getting back to work.

ESTABLISHING GOALS FOR OPIOID THERAPY FOR CHRONIC PAIN

- It is best to establish goals before embarking on a course of long-term opioid therapy, including criteria of success and failure
<http://www.coperems.org>
- Focus on achievement of life goals. Do not accept the goal of “no pain” or the goal of “less pain” in isolation from life goals
- If patient resists, ask “ how would your life be different if you had significantly less pain?” Then explain that this is the life you will aim for together, which may or may not involve significant pain reduction.

MEASURING PROGRESS IN CHRONIC PAIN CARE

- Measuring pain intensity alone is not adequate
 - wrong goals
 - wrong patients
 - wrong understanding
- Need multidimensional assessment
 - Function, both physical and role, personal activity
 - Sleep, depression, anxiety
 - Is life moving forward again?
 - <http://paintracker.uwmedicine.org>

7

Re-evaluate benefits and harms of opioids, and continue therapy only as a deliberate decision

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- Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.
- If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

(Recommendation category: A; Evidence type: 4)

MEASURING PROGRESS IN RESPONSE TO LONG-TERM OPIOID THERAPY

- Short-term and long-term opioid therapy are different therapies, even if same meds used
- Short-term response (weeks-months) does not predict long-term response (months-years)
- Patients themselves tend to overestimate the benefit of therapy based on experiences with starting and stopping opioid therapy
- Pay attention to patients' report of current level of pain and function, but don't be distracted by claims that "I would be much worse without these opioids"

8

Evaluate and address risks for opioid-related harms

- Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms.
- Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use, are present.

(Recommendation category: A; Evidence type: 4)

TWO SOURCES OF RISK FOR LONG-TERM OPIOID THERAPY

- Medication regimen
 - Opioid dose
 - Long-acting or extended-release opioids
 - Concurrent sedative use
- Patient characteristics
 - Current or past substance use disorders (tobacco)
 - Inadequately treated mental health disorders (PTSD)
 - Young age
 - Previous opioid overdose

RISKS OF LONG-TERM OPIOID THERAPY TO PATIENTS

- Decreased function/return to work (cohorts)
- Hyperalgesia
- Tolerance (invisible?)
- Dependence (lifelong?)
- Misuse (due to above)
- Abuse (25%) and addiction (10%)

RISKS OF LONG-TERM OPIOID THERAPY TO PATIENTS

- Hypogonadism (infertility, low libido)
- Masked psychiatric disorder (PTSD)
- Induced depression (duration > dose)
- Overdose, death, emergency department visits (>700,000 in 2012)
- Motor vehicle crashes (OR=1.2-1.5)
- Falls, fractures, sedation, delirium

RISKS OF LONG-TERM OPIOID THERAPY TO FAMILY AND FRIENDS

- Abuse
 - 12th graders: 10% 2010 → 6% 2014
- Accidental overdose, death
 - Heroin deaths doubled 2010 – 2012
- Addiction

BACK TO MS. CHRISTIE

46 Y/O FEMALE WITH FIBROMYALGIA

- Initially managed on gabapentin, began opioids in emergency department after motor vehicle crash
- These were continued because of reports of continued severe pain and dysfunction
- Opioid therapy slipped from short-term to long-term without explicit examination of goals, risks and benefits of long-term opioid therapy

BACK TO MS. CHRISTIE

46 Y/O FEMALE WITH FIBROMYALGIA

- Ms. Christie should not have been given more than 3-7 days of opioids for her back strain from motor vehicle crash
- When she saw her primary care provider 2 weeks later, her opioid therapy was now treating her FM, not her back strain from motor vehicle crash
- Her report of improvement a week after her primary care provider doubled her OxyContin dose, is not sounds promising, but is not a good indicator of her likelihood of benefit from long-term therapy

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Dosing and Titrating Opioids

**Clinician Outreach and
Communication Activity
(COCA) Call
August 17, 2016**



Objectives

At the conclusion of this session, the participant will be able to:

- ❑ Describe the evidence for the association between opioid dosage and opioid therapy benefits and harms.
- ❑ Compare and contrast immediate release and extended-release/long-acting opioid formulations.
- ❑ Identify methods for calculating morphine milligram equivalent dosage.
- ❑ List the steps for titrating opioids to specific dosage thresholds.
- ❑ Identify best practices for opioid tapering and discontinuation.



CDC Guideline for Prescribing Opioids for Chronic Pain:

Dosing and Titration of Opioids

Deborah Dowell, MD, MPH

August 17, 2016

Evidence does not support safety of ER/LA opioids relative to immediate-release opioids

- Did not find evidence that ER/LA opioids are more effective or safer than immediate-release opioids
- Higher overdose risk initiating treatment with ER/LA opioids than with immediate-release opioids
- Disproportionate numbers of overdose deaths associated with methadone

4

Use immediate-release opioids when starting

- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

(Recommendation category A: Evidence type: 4)

Additional cautions for

- *Methadone*
- *Transdermal fentanyl*
- *Immediate-release opioids combined with ER/LA opioids*

Higher dosages add risk without clear benefit

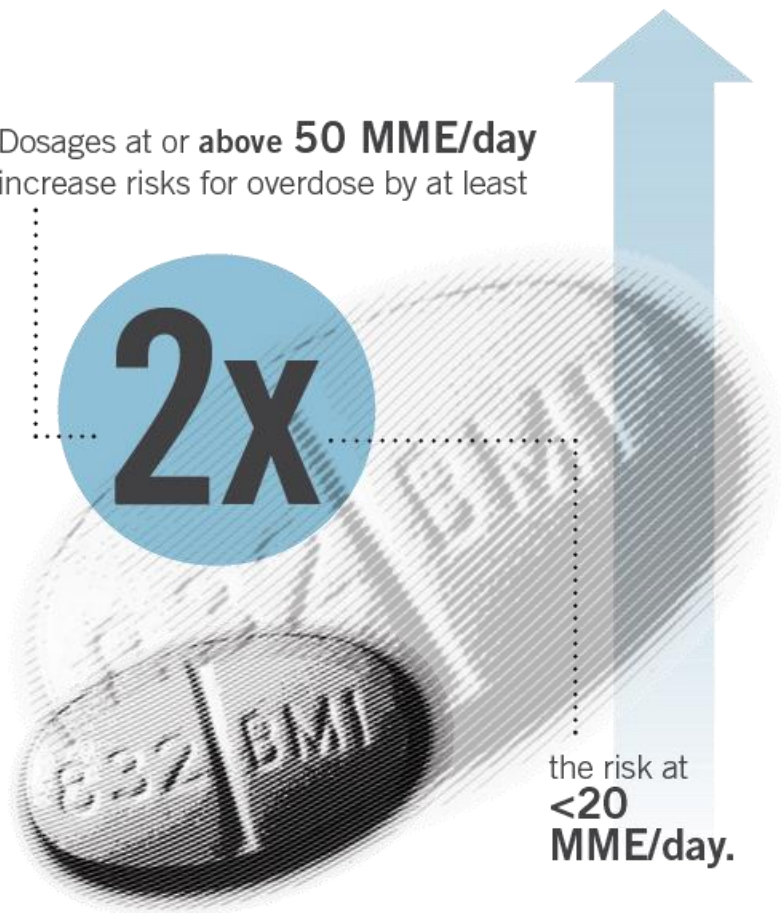
- Benefits of high-dose opioids for chronic pain not established
- RCT*: no difference in pain, function between
 - Liberal dose escalation (average 52 MME)
 - Maintenance of current dosage (average 40 MME)
- Opioid use associated with dose-dependent increased risk of serious harms, including fatal and nonfatal overdose

*Naliboff BD, Wu SM, Schieffer B, et al. A randomized trial of 2 prescription strategies for opioid treatment of chronic nonmalignant pain. *J Pain*. 2011;12(2):288-296.

Dosages at or above **50 MME/day**
increase risks for overdose by at least

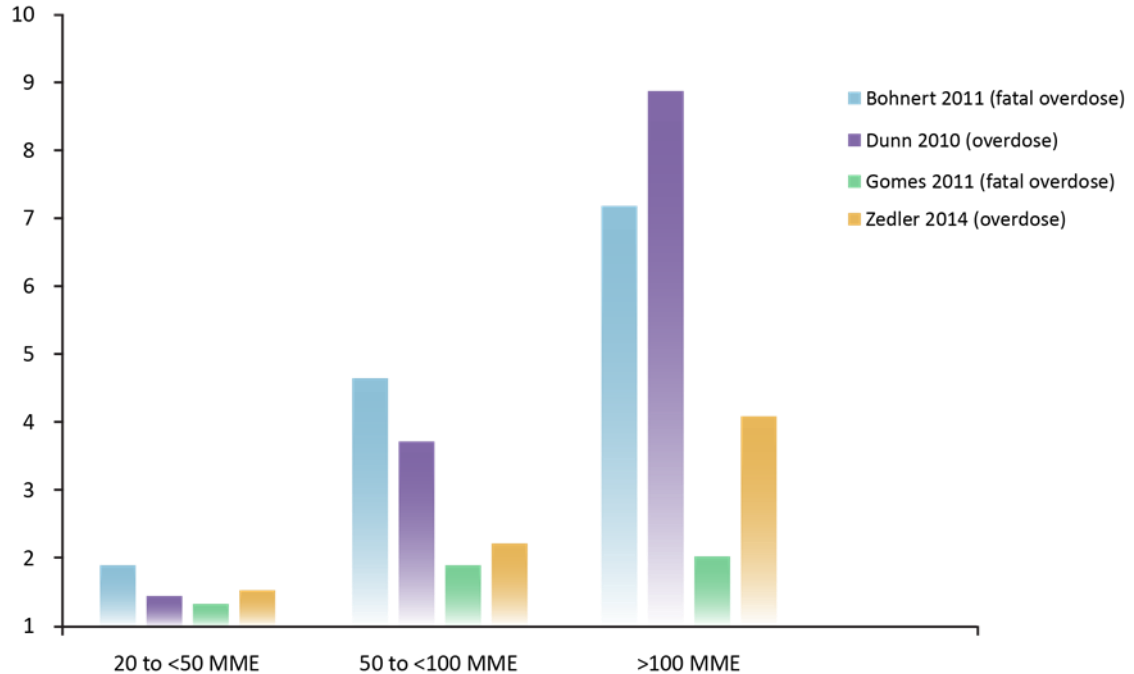
2x

the risk at
**<20
MME/day.**

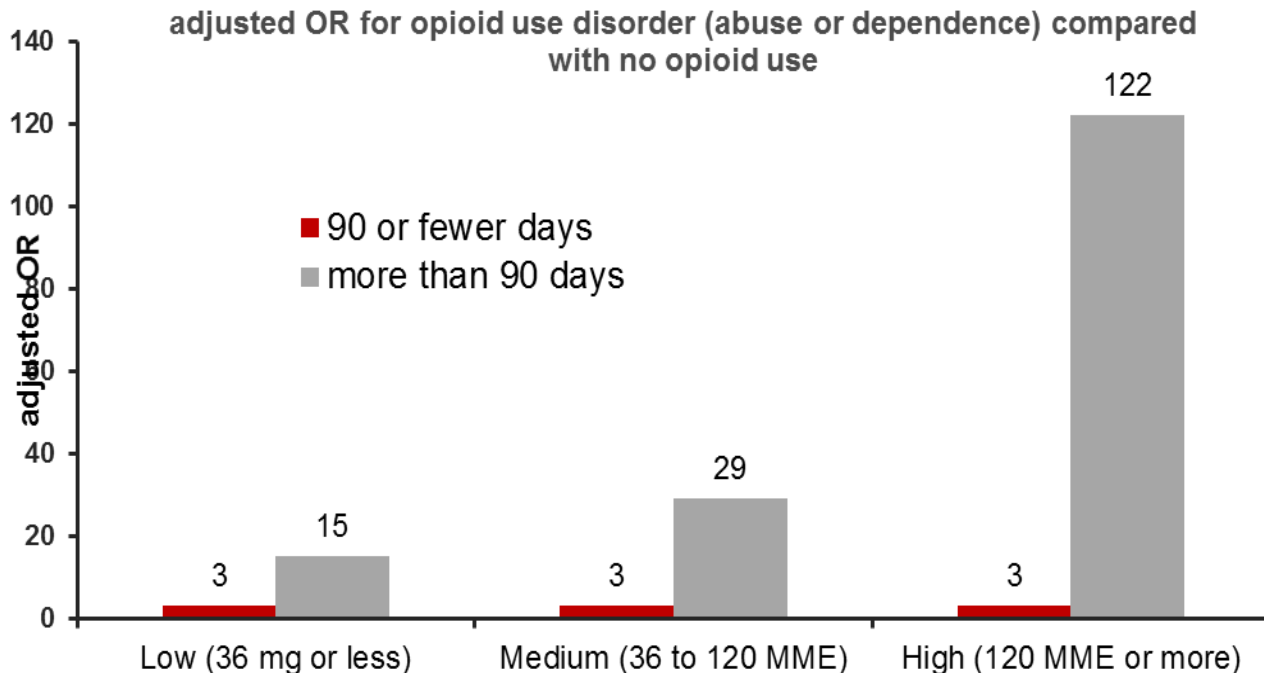


Overdose risk increases with opioid dosage

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



Higher opioid dosages associated with opioid use disorder



Edlund, MJ et al. The role of opioid prescription in incident opioid abuse & dependence among individuals with chronic noncancer pain. *Clin J Pain* 2014; 30: 557-564.

5

Use caution at any dose and avoid increasing to high dosages

- When opioids are started, clinicians should prescribe the lowest effective dosage.
- Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day.

(Recommendation category A: Evidence type: 3)

What about patients already taking high dosages?

- Offer the opportunity to reevaluate continuation of high-dosage opioids in light of recent evidence
- For patients who agree to taper opioids to lower dosages, collaborate on a tapering plan

Calculate MME

1

DETERMINE the total daily amount of each opioid the patient takes.

2

CONVERT each to MMEs—multiply the dose for each opioid by the conversion factor. (*see table*)

3

ADD them together.



Calculating morphine milligram equivalents (MME)

CAUTION:
Do not use
to convert
one opioid
to another

OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥ 61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

7

Offer a taper if opioids cause harm or are not helping

- Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation.
- Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.
- If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

(Recommendation category A: Evidence type: 4)

Taper slowly enough to minimize withdrawal

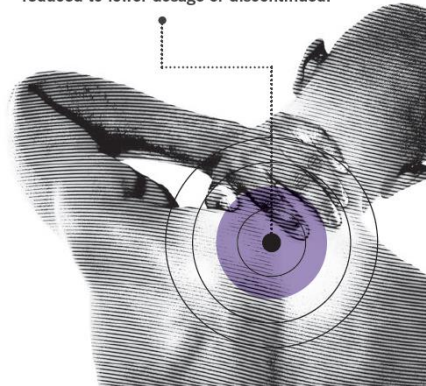
- 10% per week is a reasonable starting point
- Some patients do better with slower tapers - 10%/month
- Consider more rapid taper when needed for safety
- Access appropriate expertise during pregnancy
- Optimize pain management and support
 - Anticipate hyperalgesia immediately after tapering
 - Over the long term, most patients report improved function without worse pain

POCKET GUIDE: TAPERING OPIOIDS FOR CHRONIC PAIN



Follow up regularly with patients to determine whether opioids are meeting treatment goals and whether opioids can be reduced to lower dosage or discontinued.

New Resource



Available under the Clinical Tools section of our Guideline resources:
<http://www.cdc.gov/drugoverdose/prescribing/resources.html>

CDC Guideline for Prescribing Opioids
for Chronic Pain

DOSING AND TITRATION OF OPIOIDS



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#Psychiatry and Behavioral Science

#Bioethics and Humanities

CASE: MS. BROWN

- Ms. Brown is 67 years old and has spinal stenosis
- She has had steadily worsening symptoms of leg pain, lower back pain, leg numbness and tingling, and difficulty walking
- She now finds it difficult to start moving and ambulating in the mornings
- She is motivated to get as well as she can without medication, and has been doing aqua aerobics and graded exercise under the supervision of therapists
- She has tried amitriptyline, gabapentin, and tramadol, but none of these helped
- Her clinician suggested a trial of low dose strong opioid
- She agreed

WHICH OPIOID?

- Choose something simple with simple pharmacokinetics and pharmacodynamics
- This makes the treatment much safer and easier to manage by patients
- Do not use any of the long acting opioids when starting opioid therapy in an opioid naïve patient
- Long acting opioids include ER/LA opioids, methadone and transdermal fentanyl (fentanyl patches)

4

When starting opioids for chronic pain, prescribe IR not ER/LA opioids

- Choose predictable pharmacology to minimize overdose risk
- In general, avoid IR combined with ER/LA opioids
- Methadone should not be the first choice for an ER/LA opioid
 - Only providers familiar with methadone's unique risk and who are prepared to educate and closely monitor their patients should consider prescribing it for pain.
- Only consider prescribing transdermal fentanyl if familiar with the dosing and absorption properties and prepared to educate patients about its use.

From the supporting text for Recommendation #4 from the *CDC Guideline for Prescribing Opioids for Chronic Pain*. Recommendation category: A; Evidence type: 4

WHY NOT START WITH LONG ACTING OPIOIDS?

- Dosage forms for ER/LA and transdermal fentanyl are too high for opioid naïve patients, especially elderly patients
- Most patients prefer taking opioids as needed and not round the clock
- Most patients find it easier to control their usage if they are taking opioid as needed and not round the clock
- Overall doses tend to be much lower if IR opioids are taken intermittently and no opioid is taken round the clock

IS THERE A ROLE FOR LONG-ACTING OPIOIDS?

- Yes, but not at the start of treatment
- Yes, when treating end-of-life pain and some long-term pain conditions
- Yes, when the patient has difficulty controlling usage (e.g. has a substance use disorder)
- Never in conjunction with IR opioids except during palliative or end-of-life pain care

WHY NOT METHADONE?

- Methadone has very complicated pharmacokinetics
- There are possible cardiac effects including QT prolongation
- There are many drug interactions
- Clearance is idiosyncratic, unpredictable and usually delayed
- Methadone is hard to get off
- Methadone should be reserved for specialists, cancer pain or addiction treatment

WHY NOT TRANSDERMAL FENTANYL?

- Even the lowest dose is too high for start of therapy
- Absorption can be unreliable
- Heat (e.g. hot showers or baths) can release medication suddenly leading to overdose
- Cannot provide intermittent or as needed doses

THE CHOICE FOR MS. BROWN

2.5 mg oxycodone (1/2 tablet) every 4
hours as needed

When opioids are started, prescribe the lowest effective dose

- Use caution when prescribing opioids at any dosage
- Carefully reassess evidence of individual benefits and risks when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day
- Avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day.

(Recommendation category: A; Evidence type: 3)

AT FOLLOW-UP: MS. BROWN

- She returned to the clinic the following week and reported no improvement but tolerating opioid well and taking it 4 times daily
- Her dose was increased to try and get an effect
- After 2 further dose increases, she stabilized at 5 mg 4 hrly as needed, up to times daily

Re-evaluate benefits and harms of opioids, and continue therapy only as a deliberate decision

- Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation.
- Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.
- If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

(Recommendation category: A; Evidence type: 4)

3 MONTH FOLLOW-UP: MS. BROWN

- At her 3 month follow up she came with her daughter who said her mother was drowsy all the time, and getting out and about even less that before
- The decision was made to taper her off the opioid

HOW TO DO A STRAIGHTFORWARD TAPER

- Do not try to taper too quickly, even for someone who hasn't been on opioids for very long
- A reasonable regime would be:

10% reduction per week until off

- Warn about possible withdrawal symptoms and be prepared to treat withdrawal if it occurs

CASE: MR. CASEY

- Mr. Casey is a 55 year-old self-employed truck driver who has had back pain for 7 years, starting with a back sprain injury
- He initially had a disc protrusion but that has resolved and he now has an MRI consistent with age and a normal exam
- He has been treated with opioids since the initial sprain injury
- His current regime is 30 mg oxycontin 3 times daily with 30 mg oxycodone 6 times daily as needed (MME 405)

CASE OF MR. CASEY CONTINUED:

- He has tried other medical and non medical treatments but says none of them work
- He works night to try and make up for time lost during painful episodes
- He doesn't remember what it's like to sleep well
- His wife of 18 years recently asked him to leave because he is dragging down the family
- He is convinced that opioids are the only thing that enable to work

WHAT ARE YOU GOING TO DO?

- His opioid dose is higher than currently recommended
- His function is poor and his life is in tatters
- He is almost certainly dependent on opioids
- It will be hard to persuade him to taper and hard to achieve a taper
- He will need a lot of ancillary help if he is going to improve

Re-evaluate benefits and harms of opioids, and continue therapy only as a deliberate decision

- Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation.
- Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.
- If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

(Recommendation category: A; Evidence type: 4)

BASIC PRINCIPLES OF TAPERING IN A LONG-TERM OPIOID TREATED OR OPIOID DEPENDENT PATIENT

1. Spend time convincing the patient that tapering is the right thing to do (This may take more than one visit)
2. Taper slowly **e.g. 10% reduction per month**
3. Be prepared to stop and give it a rest for a while if it gets difficult
4. As long as the trend is downwards, the amount of time it takes doesn't matter
5. Never go up

BASIC PRINCIPLES CONTINUED:

6. If surgery or trauma intervene, always go back to the pre-event dose ASAP
 7. If it is necessary or desirable to do a rapid taper, buprenorphine is a useful tool
 8. Buprenorphine is a useful tool anyway
- GET BUPRENORPHINE TRAINING**

TAPERING OPIOIDS

- **Work with patients to taper opioids down or off when**
 - no sustained clinically meaningful improvement in pain and function
 - opioid dosages >50 MME/day without evidence of benefit
 - concurrent benzodiazepines that can't be tapered off
 - patients request dosage reduction or discontinuation
 - patients experience overdose, other serious adverse events, warning signs.
- **Taper slowly enough to minimize opioid withdrawal**
 - A decrease of 10% per week is a reasonable starting point
- **Access appropriate expertise for tapering during pregnancy**
- **Optimize nonopioid pain management and psychosocial support**

START LOW AND GO SLOW

- **Start with lowest effective dosage and increase by the smallest practical amount.**
- **If total opioid dosage ≥ 50 MME/day**
 - reassess pain, function, and treatment
 - increase frequency of follow-up; and
 - consider offering naloxone.
- **Avoid increasing opioid dosages to >90 MME/day.**
- **If escalating dosage requirements**
 - discuss other pain therapies with the patient
 - consider working with the patient to taper opioids down or off
 - consider consulting a pain specialist.

IF PATIENT IS ALREADY RECEIVING A HIGH DOSAGE

- Offer established patients already taking ≥ 90 MME/day the opportunity to re-evaluate their continued use of high opioid dosages in light of recent evidence regarding the association of opioid dosage and overdose risk.
- For patients who agree to taper opioids to lower dosages, collaborate with the patient on a tapering plan.

Assessment and Evidence-based Treatments for Opioid Use Disorder

Clinician Outreach and
Communication Activity
(COCA) Call
November 29, 2016

Objectives

At the conclusion of this session, the participant will be able to:

- ❑ Describe *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)* assessment criteria for opioid use disorder.
- ❑ Discuss the evidence for opioid use disorder medication-assisted treatment.
- ❑ List types of medications and settings used in medication-assisted therapy.
- ❑ Review considerations for buprenorphine, methadone, and naltrexone use for opioid use disorder.
- ❑ Outline the opioid taper process used when opioid harms exceed opioid benefits but opioid use disorder DSM-5 criteria are not met.



CDC Guideline for Prescribing Opioids for Chronic Pain:

Assessment of opioid use disorder and referral to evidence-based treatment

Deborah Dowell, MD, MPH

November 29, 2016

Evidence

- Prevalence of DSM-IV opioid dependence in primary care settings among patients with chronic pain on opioid therapy: 3%–26%
- Opioid agonist treatment prevents relapse
 - Methadone (full opioid agonist)
 - Buprenorphine (partial opioid agonist)
- Naltrexone (opioid antagonist) can be effective in patients who are able to continue treatment

Treat patients for opioid use disorder (OUD) if needed

- Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

(Recommendation category A: Evidence type: 2)

Opioid use disorder

- Previously classified as opioid abuse or opioid dependence (DSM-IV)
- Defined in DSM-5 as a problematic pattern of opioid use leading to clinically significant impairment or distress
 - manifested by at least two defined criteria
 - occurring within a year

Opioid Use Disorder diagnostic criteria

[first 9 of 11 criteria]

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:

1. Opioids are often taken in larger amounts or over a longer period than was intended.
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
4. Craving, or a strong desire or urge to use opioids.
5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
8. Recurrent opioid use in situations in which it is physically hazardous.
9. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.

Opioid Use Disorder diagnostic criteria

[last 2 of 11 criteria]

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:

10. Tolerance, as defined by either of the following:

- a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect.
- b. A markedly diminished effect with continued use of the same amount of an opioid.

Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.

11. Withdrawal, as manifested by either of the following:

- a. The characteristic opioid withdrawal syndrome (refer to Criteria A and B of the criteria set for opioid withdrawal).
- b. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.

Note: This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

If you suspect opioid use disorder

- Discuss your concern with your patient
- Provide an opportunity for your patient to disclose related concerns or problems
- Assess for opioid use disorder
 - Use DSM-5 criteria or
 - Arrange for assessment with a substance use disorder specialist
- Do not dismiss patients from care—use the opportunity to provide potentially lifesaving information and interventions

If patient meets criteria for opioid use disorder, offer or arrange evidence-based treatment

- Treat with medication-assisted treatment (buprenorphine or naltrexone)

or
- Arrange for medication-assisted treatment from an
 - Office-based provider (buprenorphine or naltrexone)

or
 - Opioid treatment program (buprenorphine or methadone maintenance therapy)

Buprenorphine (partial opioid agonist)

- Can be prescribed/dispensed for opioid use disorder by qualified clinicians with a DATA waiver
- Sublingual, buccal forms available with or without naloxone
- Initiate when patient in mild-moderate opioid withdrawal
- Most patients stabilized on 8 to 16 mg/day
 - MME thresholds in the CDC Guideline for Prescribing Opioids for Chronic Pain are NOT applicable to opioid agonist treatment of opioid use disorder
- Needs to be tapered gradually when discontinued

Methadone (long-acting opioid agonist)

- For treatment of opioid use disorder, can only be dispensed by an opioid treatment program (OTP)
- Patients need to go to OTP for methadone
 - usually daily early in therapy
 - limited use of take-home doses
- Length of time in methadone treatment
 - minimum of 12 months recommended
 - patients may require treatment for years
 - If stopped, must be gradual to prevent withdrawal

Naltrexone (opioid antagonist)

- Blocks effects of opioids if used--causes immediate withdrawal
 - Use only in nonpregnant adults
 - Do not start if patient is taking or recently took opioids or has signs of withdrawal
 - Start 3-10 days after last use (longer if longer-acting opioids)
- Most effective in closely supervised patients
- Naltrexone dosing forms for opioid dependence:
 - Oral tablet (daily)
 - Long-acting injectable naltrexone (every 4 weeks IM)

Resources for treatment

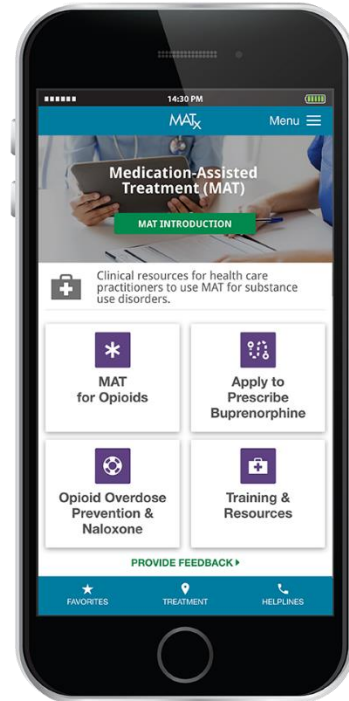
- SAMHSA's buprenorphine physician locator (http://buprenorphine.samhsa.gov/bwns_locator)
- SAMHSA's Opioid Treatment Program Directory (<http://dpt2.samhsa.gov/treatment/directory.aspx>)
- SAMHSA's Provider Clinical Support System for Opioid Therapies (<http://pcss-o.org>)
- SAMHSA's Provider's Clinical Support System for Medication-Assisted Treatment (<http://pcssmat.org>)
- HHS Treatment & Recovery Resources: (<http://www.hhs.gov/opioids/treatment-and-recovery/>)

Free electronic resources from SAMHSA at <http://store.samhsa.gov/>

- Medication-Assisted Treatment of Opioid Use Disorder Pocket Guide
- Advisory: Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder: Review and Update
- Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide

Resources for treatment

- MATx: A mobile app from SAMHSA to support medication-assisted treatment of opioid use disorder
- Available on Google Play and the App Store



Assess your community's treatment capacity for opioid use disorder

- Identify treatment resources for opioid use disorder in your community
- Work with other clinicians to ensure sufficient treatment capacity at the practice level
- Consider training and obtaining a DATA waiver that allows you to prescribe buprenorphine to treat patients with opioid use disorder

How to qualify for a waiver to prescribe buprenorphine

- Complete required training (8 hours) in the treatment and management of patients with opioid use disorders through ASAM, SAMHSA, or other organization

(See samhsa.gov/medication-assisted-treatment/training-resources/buprenorphine-physician-training)

- Apply for a waiver through SAMHSA

(See <http://www.buprenorphine.samhsa.gov>)

What about problematic opioid use that does not meet criteria for opioid use disorder?

- Offer to taper and discontinue opioids
- For patients who choose to but are unable to taper
 - Reassess for opioid use disorder
 - Offer opioid agonist therapy if criteria are met

Patients with opioid use disorder

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Opioid use disorder case

- ▶ Ron, a 50 year old man with a history of alcohol use disorder in remission and long term high dose opioid treatment after a work accident years ago
- ▶ Quit drinking alcohol after falling off a ladder at work and sustaining multiple traumatic injuries, resulting in high dose opioid therapy that was never tapered
- ▶ Taking morphine ER 90mg TID and short acting morphine 30 mg up to 4 per day
- ▶ Total opioid dose 390mg MED

Opioid use disorder case

- ▶ Since transfer from another provider, aberrant behaviors have been noted:
 - ▶ Urine test negative for prescribed morphine and positive for oxycodone. The patient admits to “borrowing” oxycodone from a friend after running out of medication due to a pain flare.
 - ▶ Admits to difficulty controlling medication use when pain flares, resulting in withdrawal when medication runs out.
 - ▶ Prescription Monitoring Program shows two additional prescribing physicians. The patient denies obtaining these medications.

Opioid use disorder diagnosis

- ▶ Takes more than intended – yes
- ▶ Desire to cut down – no
- ▶ Time spent – no
- ▶ Craving – ?? (“it’s the pain”)
- ▶ Leads to role problems – “Maybe”
- ▶ Use despite social problems – ?? (“it’s the pain”)
- ▶ Important activities given up – ?? (It’s the pain”)
- ▶ Physically hazardous – no
- ▶ Use despite medical or psychological problems – no
- ▶ Tolerance – yes
- ▶ Withdrawal - yes

Opioid use disorder diagnosis

- ▶ Presenting the diagnosis:
 - ▶ “You meet the criteria for an opioid use disorder”
 - ▶ “Trouble controlling the medication makes it unsafe”
 - ▶ “The medicine has become a problem in itself”
- ▶ Discussing treatment options
 - ▶ “Continuing the current treatment is not safe, but you do need opioid medication for the use disorder”
 - ▶ “Stabilizing the brain with medication can help a lot”
 - ▶ “Other kinds of pain treatments will work better if the brain is more stable”

Helping patients accept the diagnosis

- ▶ “All kinds of people have opioid use disorder”
- ▶ “I don’t see it as a bad person doing a bad thing”
- ▶ “Sometimes the medications cause problems due to genetic factors that we cannot anticipate”
- ▶ “Getting help for this should be like getting help for any other chronic medical problem”

Opioid use disorder treatment: buprenorphine/naloxone

- ▶ Usually recommended as first medication option – fewer barriers to treatment
- ▶ Far safer than high dose opioids for pain
- ▶ Effective no matter how high the prescribed opioid dose
- ▶ Ideally provided by the same physician (so get trained!)
- ▶ Insurance coverage for use disorder, not for pain
- ▶ Butrans patch is approved for pain, not opioid use disorder, and doses are much lower than for use disorder

Opioid use disorder treatment: methadone maintenance

- ▶ Most effective treatment in retaining patients
- ▶ Higher barrier to treatment
- ▶ Must coach patients to seek addiction treatment rather than pain management
- ▶ Provides maximum structure for patients with more severe psychosocial challenges
- ▶ Discuss take-home dose opportunities

What about high dose prescribed methadone?

- ▶ Methadone has long-acting metabolites that increase the risk of precipitated withdrawal when starting buprenorphine
- ▶ Tapering to 30-40 mg daily increases risk of withdrawal and illicit opioid use
- ▶ Higher dose prescribed methadone patients will likely require transfer to methadone maintenance
- ▶ Can offer to continue prescription pending transfer, but may require coerced transfer (transfer or taper)

Conclusions

- ▶ Opioid use disorder diagnoses can be difficult in the setting of long-term opioid prescribing
- ▶ Pharmacotherapy is the most important aspect of effective opioid use disorder treatment
- ▶ Obtaining a waiver to prescribe buprenorphine is an important management tool when there is co-occurring opioid use disorder and chronic pain
- ▶ Facilitating OUD treatment requires effective patient communication

What about problematic opioid use that does not meet criteria for OUD?

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Case of problematic opioid use

- ▶ Suzanne, 46 yr old woman with chronic neck pain following “whiplash” injury during a motor vehicle crash 5 years earlier
- ▶ She has been on opioids for these 5 years, prescribed by a colleague of yours that has recently retired
- ▶ Her opioid dose has gradually escalated due to requests, pain “flare-ups”, and other minor MVAs
- ▶ She is currently taking ER oxycodone 40mg BID, plus oxycodone 5mg for breakthrough pain, up to 5/day
- ▶ Total opioid dose 157.5mg MED

Case of problematic opioid use

the good news

- ▶ She has no history of illicit drug use and her UDTs have not shown any illicit drugs
- ▶ She has not sought out multiple prescribers for her opioids nor has she been going to the ED for extra doses, this is confirmed by consulting the state Prescription Drug Monitoring Program (PDMP)
- ▶ She had some early refill requests years ago, but your colleague told her these were not allowed and she has made no further requests

Case of problematic opioid use

the bad news

- ▶ She now reports that her pain intensity is 8/10, pain interference with general activities is 7/10, and pain interference with enjoyment of life is 9/10. She is asking for an increase in her oxycodone
 - HER OPIOID THERAPY IS NOT WORKING
- ▶ She is 5'4", 245lb, and her husband complains of her snoring
 - SHE LIKELY HAS SLEEP APNEA
- ▶ She smokes cigarettes, about 1PPD for 25 years
 - AS A SMOKER, SHE IS AT HIGH RISK FOR BAD OPIOID OUTCOMES
- ▶ She takes alprazolam 1mg PRN for panic attacks
 - OPIOIDS PLUS BENZODIAZEPINES GREATLY INCREASE RISK OF FATAL OD

Opioid taper is appropriate for this patient

- ▶ After 5 years of opioid therapy, she is not doing well. Her pain scores are high and she is seeking more opioids.
- ▶ She is at high risk for serious adverse events due to likely sleep apnea, tobacco use, benzodiazepine use
- ▶ These risks will decrease with opioid dose reduction
- ▶ Her pain level may not increase with opioid dose reduction and may decrease

Introducing opioid taper to the patient

- ▶ Explain that you can see that her opioid therapy is not working and that she is at high risk for bad events. These will not get better with further dose increases, but may get better with opioid dose decrease.
- ▶ It is usually better to introduce the idea of opioid taper at the visit before the visit when you start the taper.
- ▶ Pledge that you will not abandon the patient and that you will make sure that she has adequate pain relief.
- ▶ Patients are afraid of overwhelming pain or withdrawal and need to be reassured this will not happen.

Negotiating opioid taper with the patient

- ▶ It is always best to get the patient to agree to try taper.
- ▶ Tell the patient that there is no need to rush the taper. She can decide to pause the taper at any point. But once the taper starts, opioid doses will not be increased.
- ▶ Allow her to choose whether long-acting or short-acting opioids are tapered first. Most patients choose to taper long-acting first. She can also be offered the choice of tapering her benzodiazepine first.
- ▶ You might begin with a taper of 10% of the original dose per month, but this can be negotiated.

Making opioid taper a success for both prescriber and patient

- ▶ Explore her own ambivalence about opioid therapy. What concerns does she have about opioids? (PODS)
- ▶ Monitor depression, anxiety and insomnia before and during taper. If these are controlled, pain does not usually increase. You may need to start or adjust antidepressant medication.
- ▶ Offer the patient pain self-management resources
 - ▶ Referral
 - ▶ Books
 - ▶ Websites

Conclusions

- ▶ Opioid taper is appropriate for patients without OUD whose opioid therapy has low efficacy and high risks
- ▶ These patients are often ambivalent about opioid therapy and have their own reasons for tapering that can be elicited and supported
- ▶ Patients are fearful of opioid taper and need to be reassured that you will not abandon them to their pain
- ▶ Attention to depression, anxiety, and insomnia is crucial for successful opioid taper

Risk Mitigation Strategies to Reduce Opioid Overdoses

**Clinician Outreach and
Communication Activity
(COCA) Call
December 6, 2016**



Objectives

At the conclusion of this session, the participant will be able to:

- ❑ **Describe the evidence for opioid prescribing risk mitigation strategies.**
- ❑ **Review different opioid prescribing risk mitigation strategies.**
- ❑ **Summarize steps that clinicians can take when concerning information is discovered through prescription drug monitoring program checks and urine drug testing.**
- ❑ **Evaluate factors that increase risk for opioid overdose and determine when co-prescribing naloxone would be beneficial.**

CDC Guideline for Prescribing Opioids for Chronic Pain:

**Risk mitigation strategies:
Prescription Drug Monitoring Programs (PDMPs),
urine drug testing, and naloxone**

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December 6, 2016

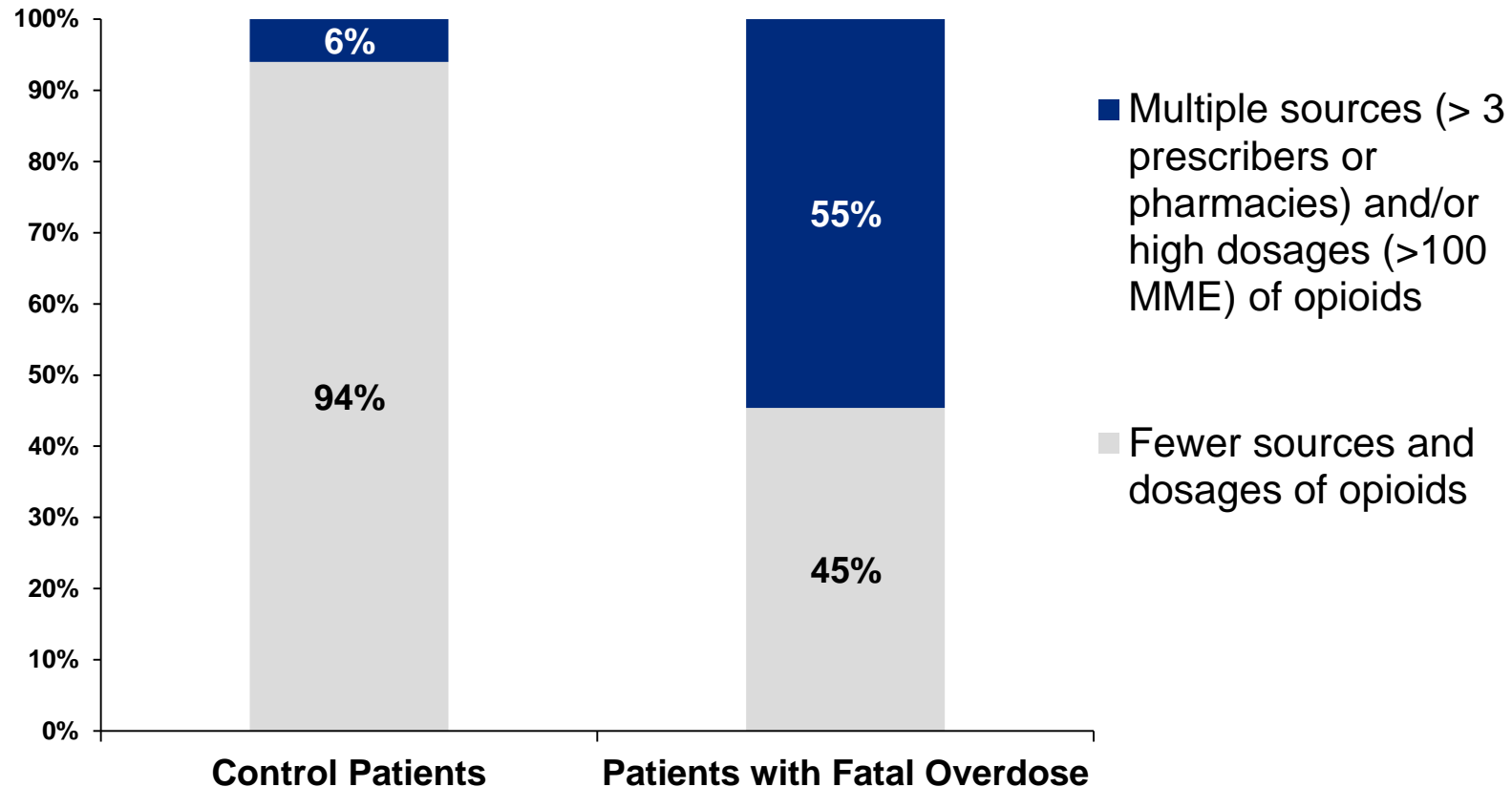
Evidence

- Most fatal prescription opioid overdoses associated with*
 - high total daily opioid dosages and/or
 - receiving opioids from multiple sourcesPDMP provides information on both these risk factors
- Urine drug tests can provide information about drug use that is not reported by the patient
- Naloxone distribution associated with decreased opioid overdose deaths at the community level**

*Gwira Baublatt et al. High-risk use by patients prescribed opioids for pain and its role in overdose deaths. *JAMA Intern Med* 2014;174:796–801

**Walley AY, Xuan Z, Hackman HH, et al. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. *BMJ* 2013;346:f174

Most prescription opioid overdose deaths involve multiple sources and/or high dosages



Gwira Baumblatt et al. High Risk Use by Patients Prescribed Opioids for Pain and its Role in Overdose Deaths. *JAMA Intern Med* 2014; 174: 796-801.

Check PDMP for high dosages and dangerous combinations

- Clinicians should review the patient's history of controlled substance prescriptions using state PDMP data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him/her at high risk for overdose.
- Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

(Recommendation category A: Evidence type: 4)

If you find concerning information in the PDMP, take action to improve patient safety

- Discuss safety concerns including increased overdose risk
- For patients receiving high total opioid dosages
 - consider tapering to a safer dosage
 - consider offering naloxone
- Consider opioid use disorder and discuss concerns
- If patients are taking benzodiazepines with opioids
 - communicate with others managing the patient
 - weigh patient goals, needs, and risks
- Do not dismiss patients from care—use the opportunity to provide potentially lifesaving information and interventions

PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

EXAMPLE FACT SHEET

WHAT IS A PDMP?

A PDMP is a statewide electronic database that tracks all controlled substance prescriptions. Authorized users can access prescription data such as medications dispensed and doses.

PDMPs improve patient safety by allowing clinicians to:

- Identify patients who are obtaining opioids from multiple providers.
- Calculate the total amount of opioids prescribed per day (in MME/day).
- Identify patients who are being prescribed other substances that may increase risk of opioids—such as benzodiazepines.

WHEN SHOULD I CHECK THE PDMP?

State requirements vary, but CDC recommends checking at least once every 3 months and consider checking prior to every opioid prescription.



WHAT SHOULD I CONSIDER WHEN PRESCRIBING OPIOIDS?



High Dosage

Talk to your patient about the risks for respiratory depression and overdose. Consider offering to taper opioids as well as prescribing naloxone for patients taking 50 MME/day or more.



Multiple Providers

Counsel your patient and coordinate care with their other prescribers to improve safety and discuss the need to obtain opioids from a single provider. Check the PDMP regularly and consider tapering or discontinuation of opioids if pattern continues.



Drug Interactions

Whenever possible, avoid prescribing opioids and benzodiazepines concurrently. Communicate with other prescribers to prioritize patient goals and weigh risks of concurrent opioid and benzodiazepine use.

WHAT SHOULD I DO IF I FIND INFORMATION ABOUT A PATIENT IN THE PDMP THAT CONCERNS ME?

Patients should not be dismissed from care based on PDMP information. Use the opportunity to provide potentially life-saving information and interventions.

- 1 Confirm that the information in the PDMP is correct.**
Check for potential data entry errors, use of a nickname or maiden name, or possible identity theft to obtain prescriptions.
- 2 Assess for possible misuse or abuse.**
Offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients who meet criteria for opioid use disorder. If you suspect diversion, urine drug testing can assist in determining whether opioids can be discontinued without causing withdrawal.
- 3 Discuss any areas of concern with your patient and emphasize your interest in their safety.**

Screenshot of the Prescription Drug Monitoring Program Fact Sheet, available at: https://www.cdc.gov/drugoverdose/pdf/pdmp_factsheet-a.pdf

Test urine for prescribed opioids and other drugs

- When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

(Recommendation category B: Evidence type: 4)

Initial urine drug testing

- Start with an immunoassay panel for
 - prescribed opioids
 - other controlled substances
 - illicit drugs that increase risk for overdose
- Do not test for drugs that would not affect patient management
- Be familiar with testing panels used in your practice and how to interpret results

Discussing urine drug testing with patients

- Explain that drug testing is used to improve safety
- Explain expected results
 - presence of prescribed medication
 - absence of unreported drugs, including illicit drugs
- Ask about use of prescribed and other drugs and if there might be unexpected results
- Provide an opportunity for patients to disclose changes in their use of prescribed opioids or other drugs

Confirming unexpected results

- Discuss unexpected results with
 - Local laboratory or toxicologist
 - Patient
- If unexpected results are not explained, confirm with a selective test such as gas or liquid chromatography/mass spectrometry

Use unexpected results to improve patient safety

- Do not dismiss patients from care based on a urine drug test result
- Consider as appropriate
 - Change in pain management strategy
 - Tapering and discontinuing opioids
 - More frequent re-evaluation
 - Offering naloxone
 - Treatment for substance use disorder

8

Evaluate and address risks for opioid-related harms

- Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms.
- Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use, are present.

(Recommendation category A: Evidence type: 4)

How to prescribe naloxone

- Resources for prescribing naloxone available at <http://prescribetoprevent.org>
 - Sample prescribing directions
 - Information for patients and their family or household members
 - Information for pharmacists
- Naloxone co-prescribing can be facilitated by collaborative practice models with pharmacists

PRESCRIBE TO PREVENT

Naloxone for Overdose Prevention

patient name	
date of birth	
patient address	
patient city, state, ZIP code	
	prescriber name
prescriber address	
prescriber city, state, ZIP code	
prescriber phone number	
Naloxone HCl 1 mg/mL 2 x 2 mL as pre-filled Luer-Lock needled syringe (NDC 76329-3369-1)	
Refills: _____	
2 x Intranasal Mucosal Atomizing Device (MAD 300)	
Refills: _____	
For suspected opioid overdose, spray 1mL in each nostril. Repeat after 3 minutes if no or minimal response.	
Pharmacist: Call 1-800-788-7999 to order MAD 300.	
prescriber signature	
date	

Risk mitigation strategies: Prescription Drug Monitoring Programs (PDMs), urine drug testing, and naloxone

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Risk mitigation strategies: case

- ▶ Beth, a 65 year old woman with rheumatoid arthritis and mild joint deformity, who is transferring care due to insurance changes
- ▶ Adherent to disease-modifying RA treatment that has been partially effective
- ▶ Prescribed #60 oxycodone/acetaminophen 5/325 mg each month for 10 years and denies adverse effects or symptoms of opioid use disorder - total opioid dose 15 mg MED
- ▶ Has no prior urine testing, prescription drug monitoring program checks, or controlled substances agreement

Risk mitigation strategy outline

- ▶ Prescription drug monitoring programs (PDMP)
- ▶ Urine toxicology testing
- ▶ Controlled substances agreements

- ▶ Apply these strategies in a lower risk case

Strategy: prescription drug monitoring program

- ▶ Can identify patients with high risk prescribing
- ▶ From a state perspective, can identify very high risk patients who may require specific interventions
- ▶ States that require PDMP checks prior to prescribing show reduction in patients with multiple prescribers
- ▶ Some evidence that physicians who have access to PDMP data prior to prescribing may prescribe more opioids
- ▶ Results may be difficult to interpret

Strategy: prescription drug monitoring program

- ▶ Case:
 - ▶ Two prescriptions in the past year from a dentist for hydrocodone/acetaminophen 5/325 mg (#10)
 - ▶ One prescription from an emergency department visit after an ankle sprain (oxycodone 5 mg #12)
- ▶ Opportunity to discuss:
 - ▶ Risks of co-prescribing of opioids
 - ▶ Potential toxicity of additional acetaminophen
 - ▶ Importance of patient reporting outside prescribing
- ▶ Document discussion in medical record

Strategy: urine toxicology testing

- ▶ Can assist in safety monitoring and diagnosing substance use disorders
- ▶ Complex to interpret
 - ▶ Screening tests vary in sensitivity and specificity
 - ▶ False positive and false negative results are common
 - ▶ Patterns of results more important than a single test
 - ▶ Best used as a trigger for closer follow up and repeat tests

Strategy: urine toxicology testing - Pitfalls

- ▶ Opioids
 - ▶ False positive: poppy seeds
 - ▶ False negative: oxycodone on opioid screens – need specific test
- ▶ Amphetamine/methamphetamine
 - ▶ False positive: bupropion, trazodone, decongestants, etc
- ▶ Benzodiazepine
 - ▶ False positive: sertraline
 - ▶ False negative: clonazepam, lorazepam

Strategy: urine toxicology testing

- ▶ Case
 - ▶ Urine toxicology negative for prescribed oxycodone
 - ▶ Specific test also negative
 - ▶ Patient reports taking medication prior to activity, not every day
 - ▶ Low dose, intermittent use can result in negative tests
- ▶ Urine toxicology testing can be useful for safely monitoring and addiction assessment, but many pitfalls
- ▶ Discuss unexpected results with the lab you are using, as test characteristics vary

Strategy: controlled substances agreement

- ▶ Common approach to informing patients of opioid risks and clinic policies, and anticipating potential problems
- ▶ Present rationale as providing informed consent for all patients regarding a potentially risky treatment
- ▶ Emphasize no dose escalation without prior consultation – “let me be the doctor”
- ▶ Can be coupled with assessment of patient side effects, ranging from sedation to constipation to depression to loss of control

Strategy: controlled substances agreement

- ▶ Case:
 - ▶ In the last year or two, the patient has noted less energy and more difficulty concentrating later in the day after taking opioids
 - ▶ Almost fell after taking two tablets on an especially active day
 - ▶ Expresses interest in additional non-medication approaches

Risk mitigation strategies – conclusions

- ▶ Important components for monitoring safety of long term opioid prescribing
- ▶ Prescription drug monitoring program and urine toxicology checks can be useful, but their limitations must be understood
- ▶ Patient education about the risks of prescribing and clinic policies provides an opportunity to avoid problems and reconsider opioid prescribing

Risk mitigation strategies: Prescription Drug Monitoring Programs (PDMPs), urine drug testing, and naloxone

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Safe management of high dose opioid case

- ▶ Mr Thomas is a 46 yr old man with low back pain persisting for 8 yrs, and initiated when he was injured at work.
- ▶ Apart from back pain, he has no other health issues and takes no medications other than opioids.
- ▶ He has not worked since the injury.
- ▶ He has some residual low back and left leg pain, and evidence on MRI of slight encroachment of L4 nerve root due to foraminal stenosis.

Safe management of high dose opioid case

- ▶ He is not considered a suitable candidate for surgery.
- ▶ Epidural steroid injections have provided some relief in the past but he is not interested in receiving any more injections because “it doesn’t last long enough to be worth it”.
- ▶ He has tried physical therapy, but feels that it has not helped and he is not willing to try more.
- ▶ He takes 30 mg methadone 3 times daily, plus oxycodone IR 10 mg, up to 6 daily
- ▶ Total opioid dose 1170mg MMD

Safe management of high dose opioid case

- ▶ He has always been a compliant patient, although he has not had a UDT since early in the course of treatment, the PDMP has never been checked, and there is no opioid agreement on file.
- ▶ The provider recently learned about the CDC Guideline for Prescribing Opioids for Chronic Pain, and when looking at the CDC's recommendations, realized that his patient was on opioid doses that were no longer considered safe.
- ▶ What must the provider do now to improve the safety of the current regime?

First

- ▶ Speak to the patient and his family about the new information that has emerged about serious safety considerations related to high dose opioids.
- ▶ Explain that new measures need to be taken in order to comply with today's standard of care.
- ▶ Explain that one measure will be to gradually taper the opioid to a safer dose, or to discontinuation.
- ▶ Explain that the taper can be done slowly so that there is no unpleasant withdrawal, that most people feel better on a lower dose, and that pain relief is not compromised.

First

- ▶ Prescribe naloxone and explain to patient and family why this has become necessary, and how and when to use it.
- ▶ If the patient is upset, wait until next visit to start the taper.



Second

- ▶ Evaluate for comorbidities that could increase risk

Comorbidities

Depression or anxiety
PTSD or history of abuse/trauma
Poor sleep
Sleep apnea
Obesity
Constipation
Risk of misuse or abuse
Cognitive impairment
Dementia
Medication issues

Recommended actions

Counseling and possible medication
Consider psychiatric referral
Consider sleep study, teach sleep hygiene
Consider formal assessment and treatment
Consider nutritional consult
Treat with diet, stool softener and gentle laxative
Get baseline from opioid risk screener
Screen for reaction times, discuss driving risks
Protect against falls
CNS depressants, anticholinergics

Third

- ▶ Get a baseline UDT
- ▶ Check the PDMP
- ▶ Write up a goal directed opioid agreement and explain why it is needed

Fourth

► Explain tapering options:

- 1) Slow taper starting with either long acting or short acting (not both)
- 2) Rapid taper with suboxone induction (not option if tapering methadone)
- 3) Adjuncts for depression or anxiety during taper (eg small dose of TCA)
- 4) If also on a benzodiazepine, choose between opioid and benzodiazepine

Fifth

Depending on results of UDT, PDMP and medical evaluation, decide upon:

- ▶ speed of taper
- ▶ possible need for immediate discontinuation (rare, only if needed for safety)
- ▶ future frequency of provision of prescriptions
- ▶ UDT schedule
- ▶ PDMP review schedule
- ▶ need for additional providers (eg psychology/psychiatry, PT, group therapy)

Fifth

- ▶ If addiction is diagnosed, refer for addiction treatment and do not prescribe opioids for pain once addiction treatment is started. Continue treating pain using non-opioid modalities.

Effectively Communicating with Patients about Opioid Therapy

**Clinician Outreach and
Communication Activity
(COCA) Call
December 13, 2016**



Objectives

At the conclusion of this session, the participant will be able to:

- ❑ Outline key talking points to communicate to a patient who has been prescribed opioid therapy.**
- ❑ Provide practical strategies to help motivate a patient's commitment to opioid therapy adjustment.**
- ❑ Apply a patient-centered, six-step process to minimize conflict when communicating opioid dosing recommendations.**

CDC Guideline for Prescribing Opioids for Chronic Pain:

Effective communication with patients
about opioid therapy

Deborah Dowell, MD, MPH

December 13, 2016

Effective communication is critical when

- Communicating important information
 - (For example, “Taking opioids with alcohol or other drugs can cause you to stop breathing and die.”)
- Motivating behavior change
 - (For example, committing to taper opioids)
- Addressing conflicts
 - (For example, “I don’t think opioids will help your headaches.”)

3

Discuss benefits and risks with patients

- Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

(Recommendation category A: Evidence type: 3)

Important points for patients about opioids

- We don't know how well opioids work long-term
- They probably won't take away your pain completely
- Opioids can cause you to stop breathing and die, especially at high doses, or if taken with alcohol or other drugs
- You could develop a serious, lifelong addiction
- They can cause constipation, dry mouth, nausea, vomiting, withdrawal, drowsiness, and might make driving unsafe
- We'll meet often to make sure they are not harming you
- I test urine and check a database showing medicines from other doctors to be sure all my patients on opioids are safe

Communicating important information

- Pause and ask the patient what they heard you say
- Correct misunderstandings
- Ask if there are questions
- Allow adequate time

Two principles for effective communication

- Approach patients with compassion
- Use relationship-building skills, including
 - reflective listening
 - empathic statements

What about patients already taking high opioid dosages?

- Explain there is now scientific evidence showing overdose risk increases at higher opioid doses
- Empathically review benefits and risks of continued high-dose opioid therapy
- Offer to work with the patient to taper to a safer dose
- Motivational interviewing can move the patient toward readiness for change

Principles of motivational interviewing

- Express empathy through reflective listening
- Develop discrepancy between clients' goals or values and their current behavior
- Avoid argument and direct confrontation
- Adjust to client resistance rather than opposing it directly
- Support self-efficacy and optimism

Miller, W.R., and Rollnick, S. *Motivational Interviewing: Preparing People To Change Addictive Behavior*. New York: Guilford Press, 1991

Express empathy through reflective listening

- Ask open-ended questions
 - For example, “What concerns do you have about opioids?”
- Listen
- Reflect
- Express appropriate empathy
 - For example, “The idea of changing your opioid dose after all these years must be frightening.”

Develop discrepancy between clients' goals or values and their current behavior

- Reflect back content from the patient
- Elicit ambivalent statements with nonjudgmental, reflective listening
- Ask about goals and how opioids help or don't help
- Reflect ambivalence back to the patient
 - For example, “You said that opioids used to control the pain, but they aren't working very well anymore. What makes you want to continue taking them the same way?”

Avoid argument and direct confrontation

- Argument and direct confrontation can reinforce a defensive, oppositional stance
- Recognize patient resistance as a signal
 - listen more carefully
 - change direction

Adjust to client resistance rather than opposing it directly

- Adjust to resistance rather than opposing it directly (also called “rolling with resistance”)
- Reflect what the patient just said in a neutral way
 - For example, “You aren’t ready to think about planning to reduce your dose yet.”
- Reframe the conversation
 - For example, “I care about you and want to help you get back to being as active as you would like.”

Support self-efficacy and optimism

- Reinforce signals that the patient is considering change
 - For example, “I think it’s great that you want to hear more about other ways to manage your pain.”
- Provide credible, clear, actionable information
 - For example, “Most people can function better without worse pain after tapering opioids. Many patients have improved pain after a taper, even though pain might briefly get worse at first.”

Principles of motivational interviewing

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Remaining patient-centered when there is a conflict

- (1) Understand the patient's concerns and expectations
- (2) Validate concerns, emotions – use empathy, normalization
- (3) Inform about reassuring features of the history and exam
- (4) Explain your recommendation given risks and benefits

(go back to (2) if needed)
- (5) Flexibly negotiate alternatives
- (6) Explore for residual concerns

(1) Understand the patient's concerns and expectations

- Understand the patient's concerns and expectations before addressing them.
- Ask open-ended questions
- Paraphrase what you hear
 - the patient is more likely to feel understood
 - you are more likely to address what really matters to the patient

(2) Validate concerns and emotions

- Use empathy
 - For example, “I can only imagine how frustrating it must be when the pain keeps you awake”
- Use normalization
 - For example, “many people feel even worse after their pain keeps them awake.”

(3) Inform about reassuring features of the history and exam

(4) Explain your recommendation given risks and benefits

- For example, explain that opioids
 - are unlikely to substantially reduce fibromyalgia pain more than temporarily
 - risks of dependence and overdose outweigh these minimal benefits
- Allow the patient to respond
- If she expresses additional concerns, or emotions, such as anger, go back to step (2):
 - Validate concerns, emotions, using empathy

(5) Flexibly negotiate alternatives

- For example, trial of a tricyclic; and re-evaluation soon

(6) Explore for residual concerns

Six steps congruent with patient-centered care

- (1) Understand the patient's concerns and expectations
- (2) Validate concerns, emotions – use empathy, normalization
- (3) Inform about reassuring features of the history and exam
- (4) Explain your recommendation given risks and benefits

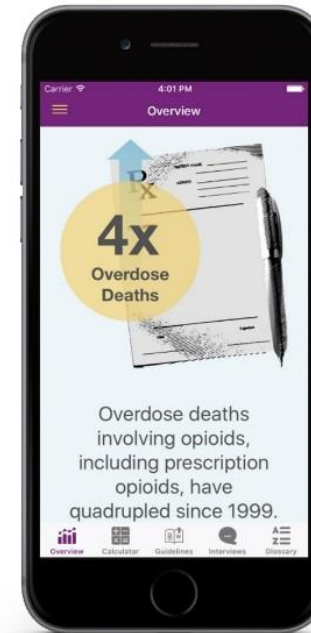
(go back to (2) if needed)
- (5) Flexibly negotiate alternatives
- (6) Explore for residual concerns

How to increase effective communication when

- Communicating important information
 - Pause and ask the patient what they heard
 - Correct misunderstandings, check for questions
- Motivating behavior change
 - Express empathy through reflective listening
 - Develop discrepancy between patient goals and behavior
 - Support self-efficacy and optimism
- Addressing conflicts
 - Understand and validate concerns and emotions
 - Explain your recommendation given benefits and risks

CDC Opioid Prescribing Guideline Mobile App

- CDC's new Opioid Guide App makes it easier to apply the recommendations into clinical practice
- Features include
 - MME Calculator
 - Prescribing Guidance
 - Motivational Interviewing Practice
- Available today, download for free from your app store (iOS or Android)
- For more information, visit:
<https://www.cdc.gov/drugoverdose/prescribing/app.html>



CDC Guideline for Prescribing Opioids
for Chronic Pain

EFFECTIVE COMMUNICATION WITH PATIENTS ABOUT OPIOID THERAPY

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Case Learning Objectives

1. Provide communication strategies for talking with patients about benefits and harms of opioids when considering transition to long-term use.
2. Provide communication strategies for talking with patients about tapering opioids.
3. Compare and contrast the communication challenges presented in the case studies with those encountered in your own clinical practice.

“Whiplash” 8 weeks after Car Crash: 37 y.o. woman

Transition Into Long-Term Opioid Therapy

- PMH/PSH: Negative
- SH: Clerical job, 2 young children, ½ ppd cigarettes, “social drinker.”
- Family history: unremarkable
- +ROS: Fatigue, poor sleep, headaches “from neck”, no weakness or numbness

EXAM: Fit. Neck limited ROM to flex, extend, rotate, and side-bend. Mild tenderness to palpate SCM, levator scapulae, trapezius, paraspinal, and occipital muscles. Neurological: Normal

Prior non-drug treatments: PT x 2 “didn’t help” week 1-3

Imaging: Normal c-spine X-rays from ED (day of injury)

Pain Metrics (“PEG”)

- **Pain Intensity:** 9/10
- **Pain Interference with Enjoyment of Life:** 9/10
- **Pain Interference with General Function:** 9/10

PHQ-4: 8

ORT: 2 “low risk”

Pain related Rx:

- Hydrocodone 10/325 6/d prn
- Methocarbamol 500 QID
- Cyclobenzaprine 10 mg prn

The Patient-Provider Dialogue (case 1)

*“Please, please refill my pain medications;
if I didn’t have them I surely couldn’t manage
my job and my family!”*

- Identify “Resistance Talk”
- Avoid arguing with her; elicit “Change Talk”
 - ① “Tell me how they are helping you?”
 - ② “What are your other concerns/fears/worries?”
 - ③ “Have you had any side-effects?”

The Patient-Provider Dialogue (case 1, continued)

“Well, you’re not just going to take away my pain pills, are you?”

- ‘Our shared goal is to help you take care of your family, and to keep you working.’
- ‘What are you concerned might happen if we reduced them very slowly?’
- ‘Would you mind if I told you what my concerns are?’
- ‘We are both looking at this together: the up-sides and the down-sides together.’

ASE #2

48 y.o. Man with CLBP 6 yrs after Spinal Fusion

Discontinuation of Long-term Opioid Therapy

PSH: L4-5 Discectomy/Laminectomy

PMH: HTN, Borderline DM, Hyperlipidemia, OSA

SH: Disabled stevedore x 6 years, married, 3 children (8,12,14), 20 pack yr tobacco, denies alcohol

FH: DM, HTN, Lung cancer

+ROS: Fatigue, poor sleep, cough, constipation, poor libido

Pain Metrics (“PEG” tool)

- Pain Intensity: 9/10
- Pain Interference with Enjoyment of Life: 9/10
- Pain Interference with General Function: 9/10

PHQ-4: 6

ORT: 6 “moderate risk”

UDTs: compliant

PDMP: consistent

Pain Rx:

Opioids: Morphine ER 60 mg BID, Hydrocodone 10/325 x8/d

Non-opioids: Carisoprodol 300 TID, Lorazepam 2 mg prn sleep

CASE #2

48 y.o. Man with CLBP 6 yrs after Spinal Fusion

Discontinuation of Long-term Opioid Therapy (continued)

Physical Exam: BP 154/94, BMI 32

- Limping and grimacing when moves
- Gait normal
- Spine: Palpation tenderness axial and paravertebral lumbo-sacral back; ROM limited due to pain; SLRs LBP only; SIJ palpation and FABERE normal
- Neurologic: Cognition and affect normal; No motor atrophy or weakness to LE motor testing, reflex exam normal; non-dermatomal dysesthetic light touch.

Imaging:

- X-Ray (flex/ext) c/w described surgery, no migration of screws, no fracture, no abnormal motion
- Magnetic resonance image (MRI) 8 weeks ago: "...s/p L4-5 lam'y, disc space narrowing, moderate degenerative facet disease..."

“Established patients already taking high dosages of opioids, as well as patients transferring from other clinicians...”

Centers for Disease Control and Prevention MMWR March 15, 2016; 65:p23

- “...tapering opioids can be **especially challenging** after years on high dosages.” Go slow if safety allows.
- **Offer the opportunity** to re-evaluate continued use of higher dose opioids in light of recent evidence regarding risks
- “**empathically review benefits and risks** of continued high-dosage opioid therapy” and “offer to **work with the patient to taper** opioids to safer dosages”
- “**very slow opioid tapers as well as pauses** in the taper to allow gradual accommodation to lower opioid dosages.”
- Be aware that **anxiety, depression, and opioid use disorder** “**might be unmasked by an opioid taper**”

The Patient-Provider Dialogue (case 2)

“But doc, I can’t even manage on my current dose; I really do need more, not less!”

- Identify “Resistance Talk”—pushing hard will lead to:
 - *“No way I can taper!”*
 - *“My life is as bad as it can be”*
 - *“What do you want me to do, lay in bed all day?”*

The Patient-Provider Dialogue (case 2 continued)

“But doc, I can’t even manage on my current dose; I really do need more, not less!”

- Avoid arguing with him; elicit “Change Talk”
 - ① “Tell me how they are helping you?”
 - ② “What are your other concerns/fears/worries?”
 - ③ “Have you had any side-effects?”
 - *Elicit: Symptoms of depression or addiction without using these words*
 - *Elicit: Tolerance, withdrawal, control problems*

Skillful Empathic Communication

1. Reflective listening is an opportunity for understanding your patient's story.
2. Non-judgmental language supports collaborative treatment planning.
3. Affirmative statements enable change by persuasion, not by argument.
4. An agreed upon opioid taper plan for your patient can result from shared medical decision-making.