Assessing Benefits and Harms of Opioid Therapy for Chronic Pain

Clinician Outreach and Communication Activity (COCA) Call

August 3, 2016

Office of Public Health Preparedness and Response
Division of Emergency Operations

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Planners have reviewed content to ensure there is no bias.

This presentation will not include any discussion of the unlabeled use of a product or products under investigational use.

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.**

Save-the-Dates

Mark your calendar for the upcoming opioid prescribing call

Call No.	Date	Topic
1	June 22	Guideline for Prescribing Opioids for Chronic Pain
2	July 27	Non-Opioid Treatments
3	August 3	Assessing Benefits and Harms of Opioid Therapy
4	August 17	Dosing and Titration of Opioids

TODAY'S PRESENTER

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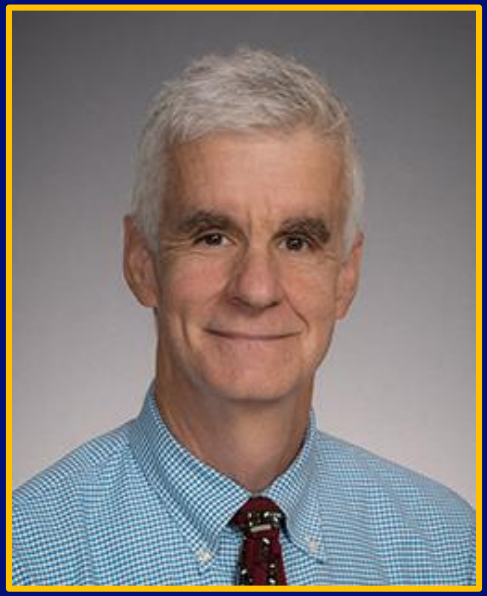
Centers for Disease Control and Prevention

TODAY'S PRESENTER



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Disclaimer

The findings and conclusions in this presentation are those of the author(s) and do not necessarily represent the views of the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry

CDC Guideline for Prescribing Opioids for Chronic Pain:

Assessing Benefits and Harms of Opioid Therapy

Deborah Dowell, MD, MPH

August 3, 2016

Centers for Disease Control and Prevention
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CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

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

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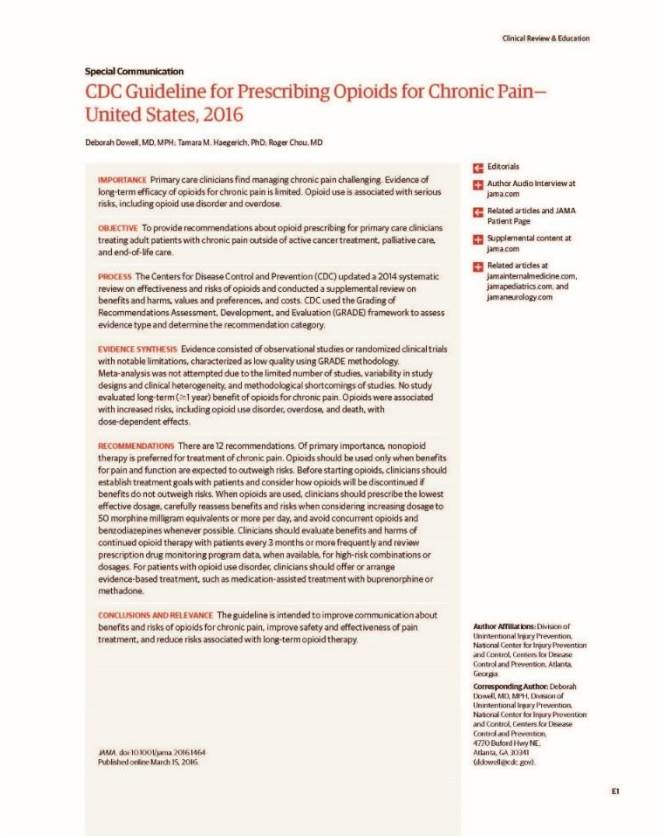

Clinical Review & Education

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.

PROCESS 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.

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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

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

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)

Establish and measure progress toward goals

2

- 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

Evaluate and address risks for opioid-related harms

8

- 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: ≥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

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

7

- 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?

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- www.cdc.gov/drugoverdose
- www.cdc.gov/drugoverdose/prescribing/guideline

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CDC Guideline for Prescribing Opioids
for Chronic Pain

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.

Opioids not first-line or routine therapy for chronic pain

1

- 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

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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

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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.

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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.

Establish and measure progress toward goals

2

- 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.

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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
  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.

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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

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

7

- 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.
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(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"

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Evaluate and address risks for opioid-related harms

8

- 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

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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%)

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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

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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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  - State your name
  - Listen for the operator to call your name
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When: A few days after the live call

What: All call recordings (audio, webinar, and transcript)

Where: On the COCA Call webpage

http://emergency.cdc.gov/coca/calls/2016/callinfo_080316.asp

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Save-the-Dates

Mark your calendar for the upcoming opioid prescribing call

Call No.	Date	Topic
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Upcoming COCA Call
registration is not required

Updated Interim Zika Clinical Guidance for Pregnant Women and Data on Contraceptive Use to Decrease Zika-affected Pregnancies

- **Date: Tuesday, August 9, 2016**
- **Time: 2:00 – 3:00 pm (Eastern)**
- **Presenters:**
  - Dr. Charlan D. Kroelinger – CDC
  - Dr. Erin Berry-Bibee – CDC
  - Dr. Titilope Oduyebo – CDC

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