Assessment and Evidence-based Treatments for Opioid Use Disorder

Clinician Outreach and Communication Activity (COCA) Call

November 29, 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 include 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 *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.

Save-the-Dates

Mark your calendar for the upcoming opioid prescribing calls

Date	Topic
November 29	Assessment and Evidence-based Treatments for Opioid Use Disorder
December 6	Risk Mitigation Strategies
December 13	Effective Communication with Patients about Opioid Therapy

TODAY'S PRESENTER

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TODAY'S PRESENTER

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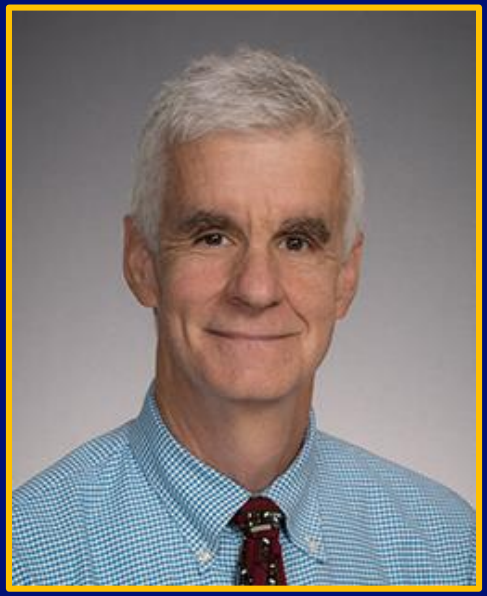

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CDC Guideline for Prescribing Opioids for Chronic Pain:

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

Deborah Dowell, MD, MPH

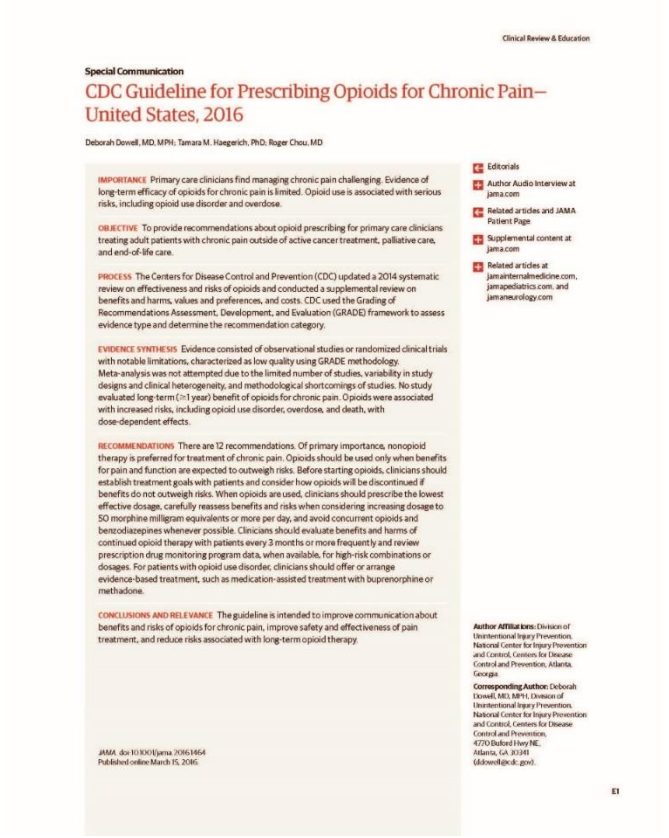
November 29, 2016

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 65 / No. 1
March 18, 2016

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



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.

Editorials
Author Audio Interview at jama.com
Related articles and JAMA Patient Page
Supplemental content at jama.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

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The Journal of the American Medical Association

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

12

- 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.

From http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf

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.

From http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf

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

GET IT ON Google Play

Download on 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 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

Connect With Us

Find more information on drug overdose and the Guideline:

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

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Find out more about Injury Center social media:

- www.cdc.gov/injury/socialmedia

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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BIOETHICS AND HUMANITIES

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

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Date	Topic
June 22	Guideline for Prescribing Opioids for Chronic Pain
July 27	Non-Opioid Treatments
August 3	Assessing Benefits and Harms of Opioid Therapy
August 17	Dosing and Titration of Opioids

Upcoming COCA Call
registration is not required

Updated CDC Zika Laboratory Testing Guidance

- **Date: Thursday, December 1, 2016**
- **Time: 2:00 – 3:00 pm (Eastern)**
- **Presenters:**
  - Dr. Grace Kubin – Association of Public Health Laboratories
  - Dr. Matthew J. Binnicker– American Society of Microbiology
  - Dr. Christy Ottendorfer– CDC

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Those who participated in today's COCA Call and who wish to receive continuing education should complete the online evaluation by December 28, 2016 with the course code WC2286. Those who will participate in the on demand activity and wish to receive continuing education should complete the online evaluation between December 29 , 2016 and November 28, 2018 will use course code WD2286.

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