#### **New CDC Opioid Guidelines** What changed and what now for pain?

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#### Disclosures

Faculty for this CE activity, have no relevant financial relationship(s) with ineligible companies to disclose.

#### **Abbreviations**

- CDC: Centers for Disease Control and Prevention
- CNS: Central nervous system
- FDA: Food and Drug Administration
- HHS: US Department of Health and Human Services
- MME: Morphine milligram equivalent
- MOUD: Medications for opioid use disorder
- PDMP: Prescription drug monitoring program
- SUD: Substance use disorder

#### **Learning Objectives**

- Recognize the impact, including unintentional consequences, of the 2016 CDC Opioid Prescribing Guideline.
- Explain the CDC's rationale for updating the 2016 CDC
  Opioid Prescribing Guideline.
- Summarize major additions and changes to the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain.
- Apply the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain to a patient case scenario for a patient with pain.

- Which trend in prescribing has been observed in non-cancer patients following the release of the 2016 CDC Opioid Prescribing Guideline?

   An increase in opioid refill rates for treatment of acute pain
   A decrease in the initial amount of filled opioids post-surgery
  - c. An increase in high dose opioid prescribing (MME >50)

- 2. Which of the following is a reason given to why the CDC decided to update the 2016 CDC Opioid Prescribing Guideline?
  - a. The availability of new evidence on nonopioid treatment of chronic pain
  - b. The need to re-define guidelines to remove focus on acute pain management
  - c. The public's demand for clarification of the 2016 prescribing guidance
  - d. The approval of multiple new drugs for the treatment of chronic pain

- 3. Which of the following was a change made in the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain?
  - a. A narrower definition for primary care provider was utilized
  - b. Guidance for acute and subacute pain management has been removed
  - c. Additional information on opioid tapering is provided
  - d. Recommendations for patients receiving palliative or end of life care have been added

4. According to the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain, what is the most appropriate prescribing recommendation for the following patient to take at home?

TE is a 36 yo female is an opioid-naïve patient being treated for pain following a minor oral surgery with low bleed risk.

- Past medical history: depression and seasonal allergies
- Current medications: bupropion (scheduled) and loratadine (as needed)
- Pain currently controlled (pain score 0) with local anesthesia

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- a. NSAID therapy is recommended and as effective as opioid therapy
- b. Extended-release opioid therapy is recommended over immediate-release opioid therapy
- c. Scheduled/around the clock opioid therapy is recommended over as needed opioid therapy
- d. Non-pharmacologic therapy is recommended as monotherapy

# Table of contents01<br/>Overview of the opioid<br/>crisis02<br/>Impact of the 2016<br/>Guidelines03<br/>Rationale for the 2022<br/>update

**04** Summary of major changes 05

Applying the guideline

# 01 :::: Overview of the opioid crisis

#### **Alarming statistics**

- Misuse of opioids occurs in 21-29% of patients who receive a prescription
- Opioid use disorder develops in 8-12% of patients on opioids
- Based on a 2019 National Survey, an estimated 10.1 million people in the US misused a prescription opioid in the past year
- Nearly 75% of drug overdose deaths in 2020 involved an opioid

#### Timeline



CDC data available from: www.cdc.gov/drugoverdose/data/analysis.html

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

#### Goals:

- Improve appropriate opioid prescribing
- Improve patient outcomes
- Minimize opioid-related risks such as development of OUD
- Summary:
  - 12 recommendations
  - Focused on chronic pain management
  - Designed for primary care clinicians in outpatient settings
  - Excluded active cancer treatment, palliative care, and end-of-life care





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# 02 Impact of the 2016 Guidelines



#### Distribution

#### Sponsored education and training

#### Partnerships with health systems

#### Clinical decision making tools

#### Fact sheets/summary sheets

Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. MMWR Recomm Rep. 2022.

## **Observed trends**

Acceleration in declining prescribing trends have been observed in studies
 examining:

All opioid prescriptions

High-dosage opioid prescriptions (≥90 morphine equivalent milligrams per day)

Overlapping opioid and benzodiazepine prescriptions Multiple specialties, though most significant in family medicine practitioners and surgeons

## **Observed trends (cont.)**

Temporary increases in nonopioid pain medication prescribing

#### Lower day supplies in opioid naïve patients

Lower rates of high doses (≥50 MME/d) prescriptions in opioid naïve patients

Decreased refills post minor surgical procedures

> Goldstick JE, Guy GP, Losby JL, Baldwin GT, Myers MG, Bohnert ASB. *JAMA Netw Open.* 2022. Bicket MC, Waljee J, Fernandez AC. *JAMA Netw Open.* 2021 MacLean CD, Fujii M, Ahern TP, et al.. *Pain Med.* 2019.

### **Challenges and Limitations**

- Most published studies are based on fill/refill data
- Many studies on unintended populations
  - Post-surgical patients
- Limited studies on:
  - Pain control
  - Quality of life
  - Mental health outcomes

Are decreased opioid fills related to less pain or less access?

Chen Q, Hsia HL, Overman R, et al. *Anesthesiology*. 2019. HHS Report to Congress 2020: https://www.fda.gov/media/147152/download

# 03 :::: Rationale for the 2022 update

#### **Availability of new evidence**

Benefits and risks of opioids for acute pain	Benefits and risks of opioids for chronic pain	Comparisons of opioid treatment with nonopioid pain treatments	Comparisons of dosing strategies
Opioid dose- dependent effects	Risk mitigation strategies	Opioid tapering and discontinuation	Post-surgical prescribing

Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. MMWR Recomm Rep. 2022.

#### **Unintentional consequences**

#### **Policy Makers**

- State legislation
- State medical boards
- State boards of pharmacy
- Insurers
- Pharmacy benefit managers
- Pharmacies/health systems

#### **Example policies**

- Required use of specific providers
- Pain management clinics
- Required use of specific pharmacies
- Dosing limitations
- Medication restrictions
- Day supply limits
- Required co-prescribing of naloxone
- Required PDMP monitoring

Approximately half of all states have passed legislation limiting initial opioid prescriptions for acute pain to a ≤7-day supply

## **Concerns regarding misapplication**

- Policies limit patient access to opioids and limit patient-centered decision making which may result in:
  - Abrupt dose reductions or discontinuation
  - Opioid withdrawal
  - Use of illicit opioids
  - Increased risk of overdose
  - Dismissal of patients from clinics
  - Decreased treatment for OUD
  - Application to unintended populations

Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *MMWR Recomm Rep.* 2022 HHS Report to Congress 2020: <u>https://www.fda.gov/media/147152/download</u> Kroenke K, Alford DP, Argoff C, et al. *Pain Med.* 2019.





#### No Shortcuts to Safer Opioid Prescribing

Deborsh Dowell, M.D., M.P.H., Tamara Hangerich, Ph.D., and Roger Chou, M.D.



## **Concerns regarding misapplication**

- FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering
  - FDA Drug Safety Communication [4-9-2019]

- Based on reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased.
- Events include:
  - Serious withdrawal symptoms
  - Uncontrolled pain
  - Psychological distress
  - Suicide

# Increased evidence of harm from guideline misapplication

Study type	Patient population	Summary of results
Retrospective cohort with patient interviews	n=609 Patients in San Francisco with chronic, non-cancer pain	Discontinuation of prescribed opioid pain relievers was associated with more frequent non-prescribed opioid pain reliever (AOR = 1.75, 1.45-2.11) and heroin use (AOR) = 1.57, 95% CI: 1.25-1.97)
Time to effect analysis of Medicaid claims data	n=494 Medicaid beneficiaries in Vermont who recently discontinued chronic, high dose opioids	Faster tapering was associated with increased adverse events. Each additional week of discontinuation time was associated with a 7% reduction in the probability of having opioid related adverse event ( $p < 0.01$ )

# 04 Summary of major changes

## **2022 Guiding Principles: Summary**

- 1. Assess and treat acute, subacute, and chronic pain
- 2. Recommendations are flexible, voluntary, and support individualized patient care decisions
- 3. Pain management should be multimodal and multidisciplinary
- 4. Misapplication can lead to unintentional and potentially harmful consequences
- 5. Health inequities need to be addressed in order to provide effective pain management for all persons



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#### Figure F-1. Meta-analysis of improvement in mean pain measures for opioids versus placebo

#### **Expanded clinical audience**

- Primary Care Clinicians
  - Family physicians
  - Nurse practitioners
  - Physician assistants
  - Internists
- Outpatient Clinicians
  - Dental and other oral health clinicians
  - Emergency clinicians providing pain management for patients being discharged from emergency departments
  - Surgeons
  - Occupational medicine physicians
  - Physical medicine and rehabilitation physicians
  - Neurologists
  - Obstetricians and gynecologists

## **General formatting**

- Continues 12 recommendation structure
- Simplifies recommendation language
- Adds "Implementation Considerations" for each section with additional details
  - Example:
    - 2016 Recommendation: 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. Three days or less will often be sufficient; more than seven days will rarely be needed
    - 2022 Recommendation: When opioids are needed for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.

# Expanded coverage to include acute and subacute pain

- Title change of guidelines:
  - 2016: CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016
  - **2022:** 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain
- Expanded evidence supports use of non-opioid therapy for conditions in which non-opioid therapy Is at least or more effective
  - Low back pain
  - Neck pain
  - Musculoskeletal injuries
  - Minor surgeries
- Highlights the critical nature of assessing pain during the subacute stage to ensure that opioid prescribing for acute pain does not unintentionally become long-term opioid therapy

# Emphasis on person-centered decision making

"The recommendations related to opioid dosages are not intended to be used as an inflexible, rigid standard of care; rather, they are intended to be <u>guideposts</u> to help inform <u>clinician-patient decision-</u> <u>making</u>."

"The implementation considerations offer practical insights, context, and specific examples meant to <u>further</u> <u>inform clinician-patient decision-</u> <u>making for the respective</u> recommendation and are not meant to be rigidly or inflexibly followed."
### **Increased guidance for tapering**

Determining whether, when, and how to taper opioids	Providing advice to patients prior to tapering	Pain management during tapering	Behavioral health support during tapering
Tapering rate	Management of opioid withdrawal during tapering	Challenges to tapering	Continuing high- dosage opioids

# Increased focus on health inequities and disparities in pain management

#### • Recognizes long-standing inequities in regards to:

- Race/ethnicity
- Gender
- Geographical limitations
- Affordability limitations
- Access limitations
  - Specialty physician care
  - Mental health care
  - Physical/occupational therapy
  - Exercise facilities
  - Other components of multimodal therapy

• Discusses use of non-opioid and non-pharmacologic therapy in comparison to opioid therapy

2016	2022
<ul> <li>Addresses chronic pain only</li> <li>Encourages combining opioids with nonpharmacologic and nonopioid therapy.</li> </ul>	<ul> <li>Focuses on acute pain</li> <li>Encourages use of the most effective therapy for the type of pain. '</li> <li>Recognizes role of opioids in specific acute pain scenarios</li> </ul>

2016	2022
<ul> <li>Discusses initiation of opioid therapy for chronic pain</li> </ul>	<ul> <li>Discusses non-opioid and opioid therapy for subacute and chronic pain.</li> </ul>

- Both conclude that staring opioids should be bases on a risks vs. benefit analysis and after discussion of realistic expectations with the patient.
- Both emphasize the importance of establishing treatment goals and a discontinuation plan for if goals are not met.

• Recommends use of immediate release opioids instead of extended-release or longacting opioids

2016	2022
<ul> <li>Recommends in chronic pain</li></ul>	<ul> <li>Recommends in acute,</li></ul>
only	subacute, and chronic pain

• Discusses dosing recommendations for initial dosing and dose increases

2016	2022
<ul> <li>Addresses chronic pain only</li> <li>Recommends a risk vs. benefits analysis when considering increases in dose ≥50 MME/day</li> <li>Recommends avoiding increases in dose ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day</li> </ul>	<ul> <li>Addresses acute, subacute, and chronic pain</li> <li>Does not include numerical dose limits</li> <li>Recommends to avoid increasing doses "levels likely to yield diminishing returns in benefits relative to risks to patients"</li> </ul>

• Discusses weighing risks vs. benefits of continuing opioid therapy

2016	2022
	<ul> <li>Recommends gradual tapers except for in life-threatening situations</li> </ul>

"Opioid therapy should not be discontinued abruptly, and clinicians should not rapidly reduce opioid dosages from higher dosages."

• Discusses duration of opioids needed for acute pain. Recommends prescribing for only the expected duration of pain severe enough to require opioids.

2016	2022
<ul> <li>Indicates that 3 days or less will often be sufficient, but that more than 7 days is rarely needed</li> </ul>	<ul> <li>Does not include specific duration recommendations</li> </ul>

- Discusses recommended frequency of follow-up.
- Both recommend a 1-4 week follow-up period after initiation of opioids for chronic pain.

2016	2022
<ul> <li>Addresses chronic pain only</li> <li>Recommends follow-up at least every 3 months after initial follow-up visit</li> </ul>	<ul> <li>Addresses both subacute and chronic pain</li> <li>Does not include specific timeframe for follow-up after initial follow-up visit</li> </ul>

• Discusses evaluating risks for opioid related harms and offering naloxone

2016	2022
<ul> <li>Recommends risk mitigation in patients at increased risk for opioid overdose</li> <li>Gives examples of high risk patients including those with history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use</li> </ul>	<ul> <li>Generally recommends risk mitigation.</li> <li>No examples listed directly in recommendation.</li> </ul>

• Discusses use of a state prescription drug monitoring program to gather information on other prescribed medications

2016	2022
<ul> <li>Addresses chronic pain only</li> <li>Gives recommendations on when and how frequently to check.</li> <li>"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 "</li> </ul>	<ul> <li>Addresses acute, subacute, and chronic pain</li> <li>No recommendations on when or how frequently to check</li> </ul>

• Discusses use of toxicology testing when prescribing opioids.

2016	2022
<ul> <li>Addresses chronic pain only</li> <li>Refers to toxicology testing as urine drug testing</li> <li>Recommends using before starting opioid therapy</li> <li>Recommends that annual urine drug testing is considered</li> </ul>	<ul> <li>Addresses acute, subacute, and chronic pain</li> <li>Only recommends considering use</li> </ul>

• Discusses use of central nervous system (CNS) depressants with opioids

2016	2022
<ul> <li>Makes recommendations for benzodiazepines only</li> <li>Recommends to avoid concurrent use of benzodiazepines and opioids whenever possible</li> </ul>	<ul> <li>Includes all CNS depressants</li> <li>Recommends to use caution when using benzodiazepines (or other CNS depressants</li> </ul>

• Discusses offering and arranging treatment for OUD

2016	2022
• Recommends use of evidence- based treatment with methadone or buprenorphine in combination with behavioral therapies	<ul> <li>Recommends evidence-based medications. Examples of medications not given.</li> <li>Recommends against detoxification without MOUD</li> </ul>

"Detoxification on its own, without medications for opioid use disorder, is not recommended for opioid use disorder because of increased risks for resuming drug use, overdose, and overdose death."

# **05 ...:** Applying the guideline

### **Applying guidelines**

- 1. Assess your patient. Are the guidelines intended for this patient?
  - Excludes pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care
- 2. Choose medications for acute pain based on diagnosis and available evidence
- 3. Arrange close follow-up for patients on opioids for subacute pain.
- 4. When using opioid therapy:
  - Employ frequent follow-up
  - Use a multimodal approach
  - Limit duration as appropriate
  - Use immediate release formulations
  - Frequently assess risks versus benefits of continuation
  - Frequently assess risks versus benefits of dose increases
- 5. If employing an opioid taper, supportive, high-touch, patient-specific, gradual tapers are recommended.

### **Applying guidelines**

- 6. Make individualized treatment decisions/recommendations. Guidelines are helpful and evidence-based, but should not replace person-centered clinical decision making.
  - May consider dosing and duration limitations as guidance, but should not be applied consistently without considering other patient-specific factors.
- 7. Employ risk reduction strategies for all pain management patients
  - Prioritize evidence-based risk mitigation strategies such as offering naloxone, checking PDMP data, screening/referring for SUDs, and educating patients on risks of opioid therapy
- 8. Use caution and increase monitoring in patient on concomitant opioids and CNS depressants. Avoid combination benzodiazepines and opioids if possible.
- 9. Support use of evidence-based MOUDs for treatment of patients with OUDs.
- 10. Recognize and address health-disparities in pain management. Take steps to improve access for patients with inequities.

#### "The recommendations are not intended to be implemented as absolute limits of policy or practice across populations by organizations, health care systems, or government entities."

- Which trend in prescribing has been observed in non-cancer patients following the release of the 2016 CDC Opioid Prescribing Guideline?
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#### **Pre-test question 4**

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