



Draft Updated CDC Guideline for Prescribing Opioids: Background, Overview, and Progress

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Updating the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain: background





Guidelines like the opioid prescribing guideline help ensure patients receive safe, effective pain treatment, including opioids when the benefits outweigh the risks.

Pain is one of the most common reasons adults seek medical care.

Acute pain (duration <1 month) is a physiologic response to noxious stimuli that can become pathologic, is normally sudden in onset, time limited, and often caused by injury, trauma, or medical treatments such as surgery.

Chronic pain (duration of ≥ 3 months) can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause.



Chronic pain is often interlinked with acute pain.

Chronic pain is the leading cause of disability in the U.S.

It is estimated that **~1 in 5 U.S. adults had chronic pain** in 2019.

~1 in 14 adults experienced high-impact chronic pain, defined as having pain most days or every day in the past three months that limited life or work activities.



Pain is a complex phenomenon.

Pain is influenced by many factors, including biological, psychological, and social factors.

There are substantial differences in pain treatment effectiveness.

Prevention, assessment, and treatment of pain is a persistent challenge for clinicians and health systems.

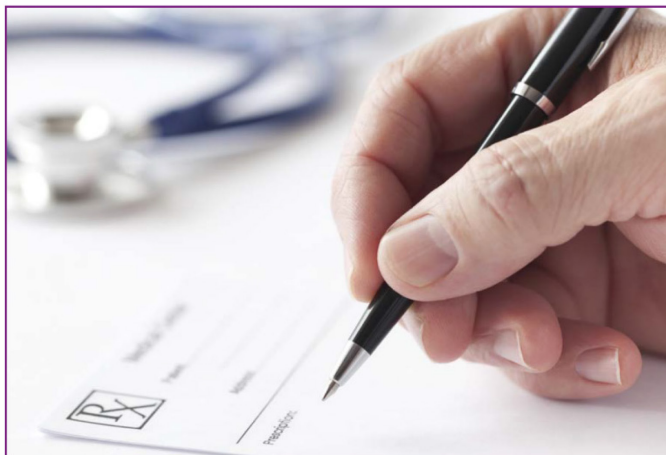


Need for opioid prescribing guideline in 2016

- Need for clear recommendations incorporating recent evidence
- Existing guidelines were several years old and did not reflect newer evidence



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.

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.

JAMA
The Journal of the American Medical Association

JAMA. 2016;315(5):1624-1645. doi:10.1001/jama.2016.1464
Published online: March 15, 2016.

← Editorials pages 1575 and 1577

+ Author Audio Interview at jama.com

← Related articles pages 1653 and 1654 and JAMA Patient Page page 1672

+ Supplemental content at jama.com

+ Related articles at jamainternalmedicine.com, jamapediatrics.com, and jamaneurology.com

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jama.com

2016 CDC Guideline: purpose, use, and primary audience

- **Recommendations for prescribing opioid pain medications:**
 - for patients 18 and older
 - in outpatient, primary care settings
 - in treating chronic pain
- **Not intended for use in cancer treatment, palliative care, or end-of-life care**
- **Primary audience: primary care clinicians**
 - family practice, internal medicine
 - physicians, nurse practitioners, physician assistants



Organization of 2016 CDC Guideline recommendations



12 recommendations were 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

2016 CDC Guideline – 12 recommendations



Determining when to initiate or continue opioids for chronic pain

1. Opioids not first-line or routine therapy for chronic pain
2. Set goals for pain and function when starting
3. Discuss expected benefits and risks with patients

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

4. Start with short-acting opioids
5. Prescribe lowest effective dose; reassess benefits and risks when increasing dose, especially to ≥ 50 MME; avoid or justify escalating dosages to ≥ 90 MME
6. Prescribe no more than needed for acute pain; 3 days often sufficient; >7 days rarely needed
7. If benefits of continuing opioids do not outweigh harms, optimize other therapies and work with patients to taper

Assessing risk and addressing harms of opioid use

8. Assess risks; consider offering naloxone
9. Check PDMP for other prescriptions, high total dosages
10. Check urine for other controlled substances
11. Avoid concurrent benzodiazepines and opioids whenever possible
12. Arrange medication-assisted treatment for opioid use disorder



2016 CDC Guideline implementation



1

Translation and communication



2

Clinician training/education



3

Health systems



4

Insurers/payers

Overall and high-risk opioid prescribing decreased at accelerated rates following 2016 CDC Guideline release

| | Pre-Guideline (1/2012) | Monthly decline prior to Guideline release (1/2012-2/2016) | Monthly decline following Guideline release (4/2016-12/2017) |
|---|-----------------------------------|---|---|
| Opioid prescribing rate/100K population | 6577 | -23.48 (CI, -26.18 to -20.78) | -56.74 (CI, -65.96 to -47.53) |
| Patients with overlapping opioid + benzodiazepine Rx (%) | 21.04% | -0.02% (CI, -0.04% to -0.01%) | -0.08% (CI, -0.08% to -0.07%) |
| High-dosage opioid Rx (≥90 MME/day)/100k population | 683 | -3.56 (95% CI, -3.79 to -3.32) | -8.00 (CI, -8.69 to -7.31) |

Some policies and practices attributed to the 2016 Guideline were misapplications of its recommendations

The 2016 Guideline does not support abrupt tapering or sudden discontinuation of opioids.

Examples of misapplications of recommendations:

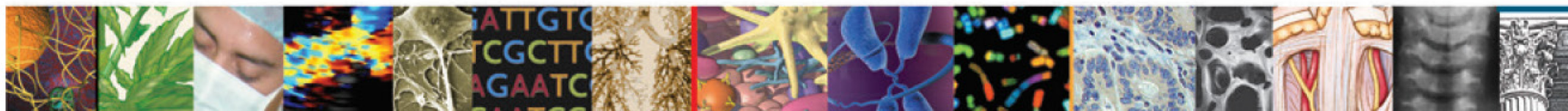
- To impose hard limits or “cutting off” opioids
- To populations outside of the 2016 Guideline’s scope (e.g., to patients with cancer pain or post-surgical pain)
- To patients receiving or starting medications for opioid use disorder

CDC responses to misapplication of the 2016 Guideline beyond its intended scope

CDC February 28, 2019 - Letter to ASCO*, ASH*, and NCCN*:

- The Guideline provides recommendations for prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.
- Guidelines addressing pain control in sickle cell disease should be used to guide decisions.
- Clinical decision-making should be based on:
 - an understanding of the patient's clinical situation, functioning, and life context
 - careful consideration of the benefits and risks of all treatment options, including opioid therapy





The NEW ENGLAND JOURNAL *of* MEDICINE

**“there are no shortcuts to
safer opioid prescribing... or
to appropriate and safe
reduction or discontinuation
of opioid use”**

Perspective
JUNE 13, 2019

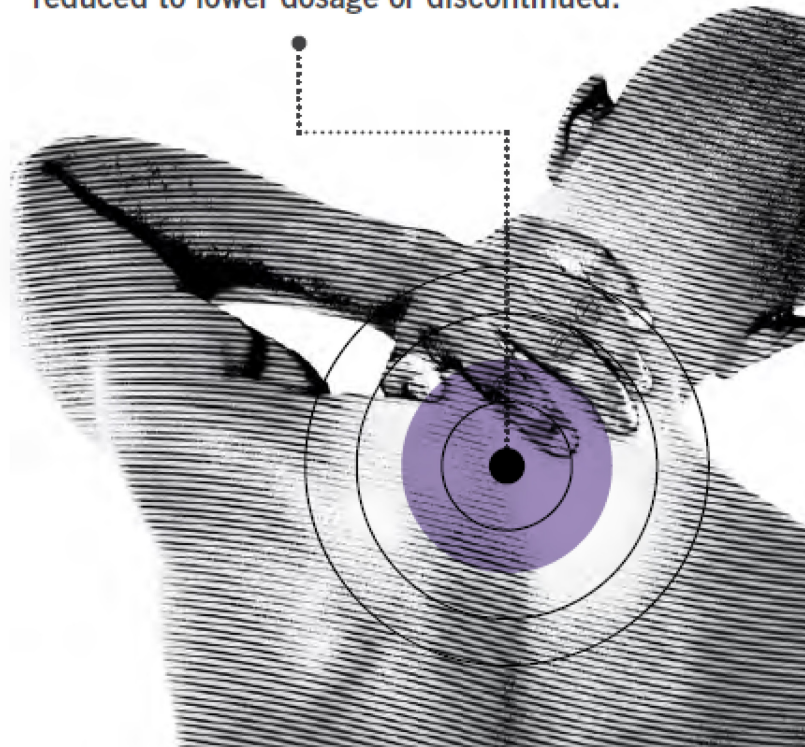
No Shortcuts to Safer Opioid Prescribing

Deborah Dowell, M.D., M.P.H., Tamara Haegerich, Ph.D., and Roger Chou, M.D.

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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.



GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

*Recommendations focus on pain lasting longer than 3 months or past the time of normal tissue healing, outside of active cancer treatment, palliative care, and end-of-life care.

Tapering plans should be individualized and should minimize symptoms of opioid withdrawal while maximizing pain treatment with nonpharmacologic therapies and nonopioid medications. In general:



Go Slow

A decrease of 10% per month is a reasonable starting point if patients have taken opioids for more than a year. A decrease of 10% per week may work for patients who have taken opioids for a shorter time (weeks to months).

Discuss the increased risk for overdose if patients quickly return to a previously prescribed higher dose.



Consult

Coordinate with specialists and treatment experts as needed—especially for patients at high risk of harm such as pregnant women or patients with an opioid use disorder.

Use extra caution during pregnancy due to possible risk to the pregnant patient and to the fetus if the patient goes into withdrawal.



Support

Make sure patients receive appropriate psychosocial support. If needed, work with mental health providers, arrange for treatment of opioid use disorder, and offer naloxone for overdose prevention.

Watch for signs of anxiety, depression, and opioid use disorder during the taper and offer support or referral as needed.



Encourage

Patient collaboration and buy-in are important to successful tapering. Tell patients that improved function and decreased pain after a taper can be expected, even though pain might initially get worse.

Tell patients "I know you can do this" or "I'll stick by you through this."

HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics

This *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics* provides advice to clinicians who are contemplating or initiating a reduction in opioid dosage or discontinuation of long-term opioid therapy for chronic pain. In each case the clinician should review the risks and benefits of the current therapy with the patient, and decide if tapering is appropriate based on individual circumstances.

Viewpoint

October 10, 2019

JAMA[®]
The Journal of the American Medical Association

ONLINE FIRST

Patient-Centered Reduction or Discontinuation of Long-term Opioid Analgesics The HHS Guide for Clinicians

Deborah Dowell, MD, MPH¹; Wilson M. Compton, MD, MPE²; Brett P. Giroir, MD³

CDC outlined the potential for a future update in the 2016 Guideline.

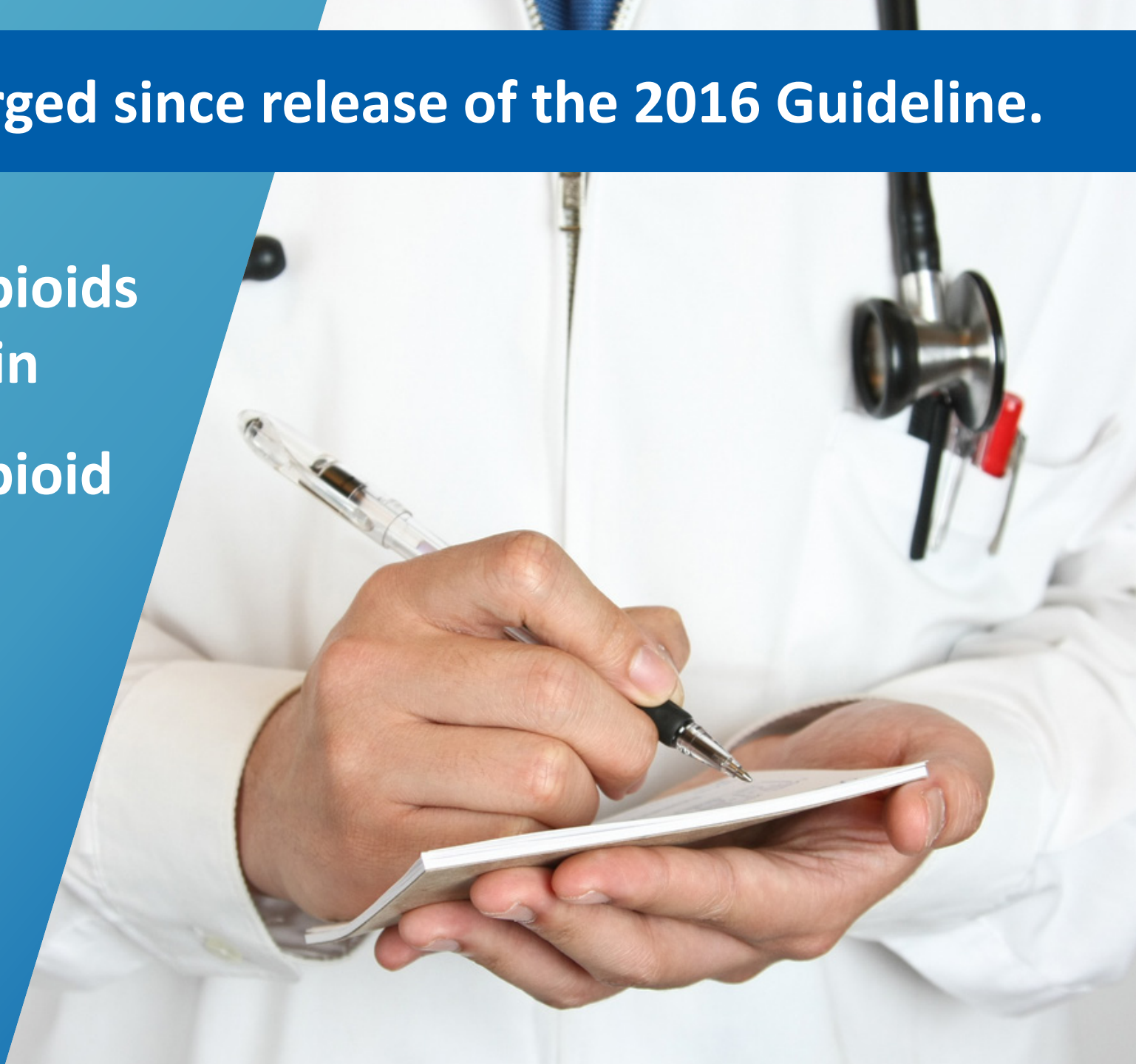
In the 2016 CDC Guideline, CDC indicated the intent to evaluate the Guideline as new evidence became available and to determine when sufficient new evidence would prompt an update.

Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain—United States, 2016. *MMWR Recomm Rep.* 2016;65(RR-1):1-49.



New evidence has emerged since release of the 2016 Guideline.

- Benefits and harms of opioids for acute and chronic pain
- Comparisons with nonopioid pain treatments
- Opioid tapering and discontinuation



Requests for CDC to provide recommendations on opioid prescribing for acute pain from:

Professional specialty societies

U.S. policymakers

Media



Updated Guideline development

Prior to drafting the updated Guideline, CDC obtained input from patients, caregivers, clinicians, and the public.



Community engagement summary

Patients, caregivers, and clinicians provided input on their lived experiences and perspectives related to pain and pain management options.

Key themes expressed included:

- Need for patients and clinicians to make shared decisions
- The impact of misapplication of the 2016 CDC Guideline
- Inconsistent access to effective pain management solutions
- Achieving reduced opioid use through diverse approaches



CDC funded the Agency for Healthcare Research and Quality (AHRQ) to conduct five systematic reviews

Chronic Pain

Noninvasive Nonpharmacological Treatment for Chronic Pain (An Update)

Nonopioid Pharmacologic Treatments for Chronic Pain

Opioid Treatments for Chronic Pain

Completed April 2020—with updates into 2022

Acute Pain

Treatments for Acute Pain Systematic Review

Treatments for Acute Episodic Migraine

*Completed December 2020—
with updates into 2022*

Evidence summaries

Several noninvasive, nonpharmacologic treatments are associated with sustained improvements in pain and/or function.

Across several common acute pain conditions:

- NSAIDs associated with similar or greater improvements in pain and function than opioids
- Evidence of diminished pain reduction over time with opioids

Evidence on long-term effectiveness of opioids remains very limited.

Evidence summaries

Serious adverse events associated with medications included

- Cardiovascular, gastrointestinal, or renal effects with NSAIDs
- Opioid use disorder and overdose with opioids

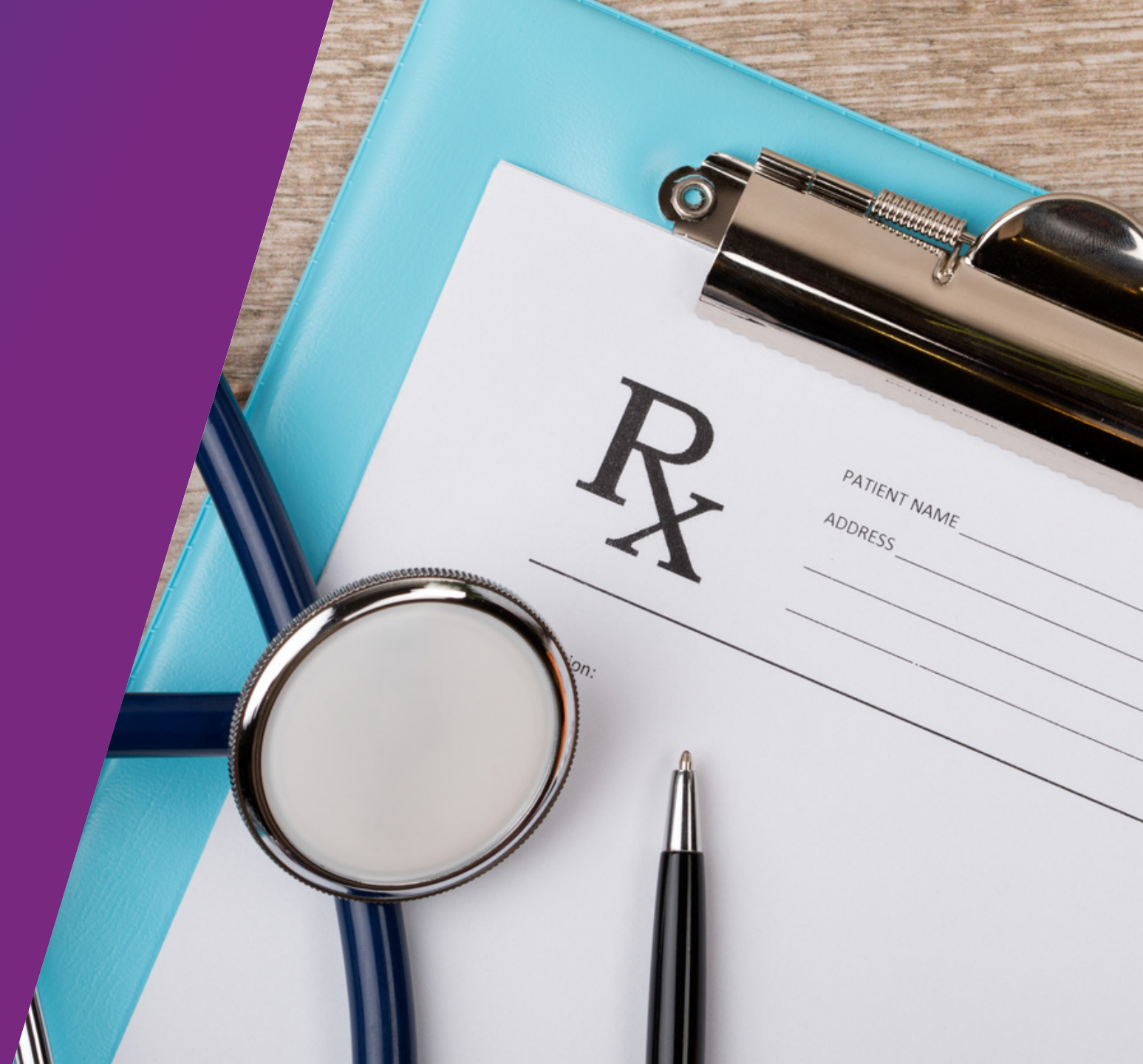
Many noninvasive, nonpharmacologic treatments are not associated with serious harms.

Evidence summaries

Tapering or discontinuing opioids in patients who have taken them long-term can be associated with significant harms, particularly if:

- Opioids are tapered rapidly
- Patients do not receive effective support

**Draft
updated
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and progress**



Information presented today is based on the DRAFT updated Guideline.

The updated Guideline is still in development.

Release is anticipated in late 2022.





The purpose of the Guideline is to support clinicians and patients to work together to create and maintain safe, consistent, and effective personal treatment plans.



Updated Guideline development

This guideline is intended to:

- Improve communication between clinicians and patients about benefits and risks of opioid therapy for pain
- Improve the safety and effectiveness of pain treatment
- Reduce risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death



The Guideline is not a law, set of regulations or requirements.

This guideline provides guidance only and does not replace clinical judgment and individualized decision-making.

- The Guideline is a tool to enhance the patient-provider relationship, informing the decision-making process and treatment planning.
- Recommendations for clinicians are intended to improve pain management and patient safety.

Updated Guideline audience

Recommendations for clinicians who are prescribing opioids for outpatients:

- Aged ≥ 18 years
- Acute (duration < 1 month) or subacute (duration of 1-3 months) pain
- Chronic (duration of ≥ 3 months) pain
- Outside of sickle cell disease-related pain management, cancer pain treatment, palliative care, and end-of-life care

Primary care clinicians

physicians, nurse practitioners, and physician assistants

Outpatient clinicians in other specialties

those managing dental and postsurgical pain and emergency clinicians providing pain management for patients being discharged from emergency departments



Updated Guideline scope

Based on input from patients, caregivers, clinicians, and the public as well as on new evidence, the updated guideline draft includes:

- Expanded guidance on acute and subacute pain
- Updated information on benefits and risks of nonpharmacologic, nonopioid pharmacologic, and opioid therapies for chronic pain
- Expanded guidance on opioid tapering and on pain management for patients already receiving opioids long-term



Updated Guideline focus areas

The updated draft recommendations address:

- 1) Determining whether or not to initiate opioids for pain
- 2) Opioid selection and dosage
- 3) Opioid duration and follow-up
- 4) Assessing risk and addressing harms of opioid use

Updated Guideline development

CDC developed the updated draft recommendations using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework.

Recommendations are made on the basis of a systematic review of the scientific evidence while considering:

- Benefits and harms
- Values and preferences
- Resource allocation (e.g., costs to patients or health systems, including clinician time)

GRADE recommendation categories

Category A:

Most patients should receive the recommended course of action

Category B:

Individual decision making required; advantages and disadvantages of a clinical action are more balanced

GRADE 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



Each draft recommendation is followed by a draft rationale for the recommendation, with considerations for implementation noted.

Upcoming public comment opportunity

Anticipated that the draft updated Guideline will be posted in the Federal Register for a 60-day public comment period by the end of 2021.



Anyone who would like to receive information related to the ongoing work of the NCIPC, specific to drug overdose prevention (including the ongoing response to the opioid overdose epidemic) as well as other drug overdose updates (e.g., pertaining to resources and tools), may sign up at www.cdc.gov/emailupdates and select topics of interest.

Subscription Topics: Injury, Violence, and Safety
Subtopic: Drug Overdose News



Our ultimate goal is to help people set and achieve personal goals for pain and function.

Conclusion

When rigorously developed and judiciously implemented, clinical practice guidelines can optimize clinical decision-making by:

- Reducing inappropriate practice variation
- Enhancing the translation of research into practice
- Increasing patient safety
- Improving healthcare quality and outcomes

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Thank you!

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.