CDC Guideline for Prescribing Opioids for Chronic Pain, 2016: Summary of CDC Response to Public Comments

Overview

CDC published a notice for public comment in the *Federal Register* (80 FR 77351) announcing the posting of the draft guideline and supporting clinical and contextual evidence reviews. The 30-day public comment period opened on December 14, 2015 and closed January 13, 2016. CDC received more than 4,350 comments in response to the federal register notice from the general public, including patients with chronic pain, clinicians, families who have lost loved ones to overdose, nongovernmental organizations, state and local entities, and others. CDC received additional comments from the public during a federal advisory committee meeting of the National Center for Injury Prevention and Control Board of Scientific Counselors (BSC) on January 28, 2016.

CDC subject matter experts carefully reviewed each comment individually and considered modifications to the guideline in response. This summary provides an overview of the more substantial changes made to the guideline after receiving comments from the public and the BSC. The areas summarized are not inclusive of all the edits made. Some less substantial clarifications were made to rationale statements supporting the recommendations that are not summarized here. When CDC posted the draft guideline for public comment, the agency also posted a summary of comments that had been made previously by peer reviewers, constituents, and stakeholders, and CDC's response to those comments. Changes made in response to these comments were reflected in the draft guideline. This summary describes changes that have been made since the draft was posted on December 14, 2015. All feedback received has strengthened and improved the quality of the guideline and CDC thanks members of the public for providing comments. The complete set of public comments may be viewed on Regulations.gov at http://www.regulations.gov/#!documentDetail;D=CDC-2015-0112-0001.

Response to Comments about Specific Recommendations

Recommendation #1

Recommendation #1 has been revised to state, "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**."

 The headline statement now emphasizes that "if opioids are used, they should be combined with nonpharmacologic and nonopioid pharmacologic therapy, as appropriate." Language has been added to the rationale to foster integrated pain management, multimodal therapy, and collaborative working relationships among other providers (e.g., behavioral health providers, pharmacists, pain specialists). Additional detail has been provided in the rationale on patient-specific selection of therapy (e.g., through evaluation of patients and confirming diagnoses, understanding the underlying mechanism for pain, and how this information can guide treatment options), risks of non-opioid pharmacologic therapy, and implementation considerations. Language has also been added to the rationale to clarify that this recommendation does not represent a "fail-first" approach.

Recommendation #5

Recommendation #5 has been revised to state, "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 considering 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."

Language has been modified to indicate that "providers should carefully reassess evidence of individual benefits and risks" when considering increasing dosage to ≥ 50 MME/day and should "avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day." The language change improves the specificity of what providers are recommended to do at ≥ 50 MME; that is, focus on reassessment of individual benefits and risks, rather than implement "additional precautions." The language change also offers more flexibility for providers regarding what to do when a decision is made to titrate dosage to ≥ 90 MME; that is, focusing on carefully justifying the decision, rather than "generally avoiding" dosages at this level. Further, a table has been added to the guideline that provides MME conversions for common medications.

Recommendation #6

Recommendation #6 has been revised to state, "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**."

• Language has been modified to indicate that "Three days or less will often be sufficient; more than seven days will rarely be needed." The language change improves the flexibility of the number of days that is indicated for opioids to usually be sufficient for acute pain. In addition, the revision removes reference to surgery and trauma in the headline statement, and provides greater detail in the rationale regarding the scope of the recommendation (e.g., "opioid treatment for post-surgical pain is outside the scope of this guideline but has been addressed elsewhere"). The guideline now acknowledges that acute pain can often be managed without opioids. Further, language has been added to the rationale about the importance of determining the etiology of acute pain.

Recommendation #11

Recommendation #11 has been revised to state, "Clinicians should avoid prescribing opioid pain medication and benzodiazepines **concurrently** whenever possible."

• The language in the headline statement has been modified to clarify that "concurrent" prescription should be avoided whenever possible (rather than implying a preference about which medication should be avoided or tapered first). Language has been added to the rationale to indicate that given that other central nervous system depressants (e.g., muscle relaxants, hypnotics) can potentiate central nervous system depression associated with opioids, clinicians should consider whether benefits outweigh risks of concurrent use of these drugs. Language has also been added to the rationale to emphasize importance of communication between primary care clinicians and mental health professionals managing the patient.

Recommendation #12

The evidence type for recommendation #12 has been modified, which currently reads, "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."

The categorization of the evidence type has been changed from type 3 to type 2, increasing the level of evidence from low to moderate, so as not to imply discounting of evidence strength due to "indirectness" (i.e., focusing on studies outside of chronic pain treatment). This change was made because the recommendation focuses on treatment for opioid use disorder generally and a level 2 (moderate) grade is more consistent with the type of evidence described in the systematic reviews cited. In the rationale for the recommendation, considerations for use of naltrexone were also added.

Response to General Comments

Introduction

- Language has been added to highlight patient-centered principles and the relationship between the provider and patient, and to acknowledge that primary care providers work within team-based care so the recommendations promote collaborative working relationships with other providers.
- Language has been added to clarify why children and adolescents < 18 years are outside the scope of the guideline (e.g., limited evidence, few medications provide information on the label regarding safety and effectiveness), while acknowledging that opioid medication use in pediatric populations is of great concern.
- Language has been added to clarify the definitions of abuse and dependence and opioid use disorder, and how such diagnoses differ from tolerance and physical dependence.
- Language has been added throughout the rationales of the recommendation statements to acknowledge the barriers for implementation (e.g., access, insurance coverage).

Methods

- The methods section has been updated to include the processes for obtaining public comment and federal advisory committee review.
- Language has been clarified around the risks of opioid use during pregnancy and maternal and fetal outcomes.
- Language has been added to clarify the selection criteria and rationale for the selection criteria for studies assessing the effectiveness of long-term opioid therapy and non-opioid treatment options (e.g., rationale for duration of studies).

Conclusion

- The conclusion now includes more information about specific translation materials that are under development by CDC and where they will be made publicly available.
- The conclusion includes more information about implementation strategies and federal partner collaboration, such as physician education and working with payers.

For more information on *CDC's Guideline for Prescribing Opioids for Chronic Pain, 2016* visit: <u>www.cdc.gov/drugoverdose/prescribing/guideline.html</u>