Overview of the Process for Updating the CDC Guideline for Prescribing Opioids

Grant Baldwin, PhD, MPH
Director
Division of Overdose Prevention
Pain is a public health concern.

Pain is a complex phenomenon that is influenced by multiple factors, including biological, psychological, and social factors.

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

Pain, in particular chronic pain, can lead to impaired physical functioning, poor mental health, reduced quality of life, and contributes to substantial morbidity and mortality each year.

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

- Economic costs of chronic pain estimated $560 to $635 billion annually.*

*Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington (DC): National Academies Press (US); 2011.
CDC strongly believes that patients with pain deserve safe and effective pain management and understands that individuals living with pain may experience challenges.
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.

Overview of the Process for Updating the Guideline
Sources of input for updating the Guideline include:

- Systematic Reviews
- Community Engagement
- Federal Advisory Committee Engagement: Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC) and BSC/NCIPC Opioid Workgroup
- Federal Partner Engagement
- Opportunities for Public Comment
- Peer Review
Scientific Evidence Reviews
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*
Noninvasive Nonpharmacological Treatment for Chronic Pain

UPDATE

- Exercise
- Multidisciplinary rehabilitation
- Acupuncture
- Cognitive behavioral therapy
- Mindfulness practices
- Massage
- Mind-body practices

Website: https://effectivehealthcare.ahrq.gov/products/noninvasive-nonpharm-pain-update/research?deliveryName=DM26365
Short-term improvement in pain and function was:

- Small with anticonvulsants
- Moderate with antidepressants in diabetic peripheral neuropathy/post-herpetic neuralgia and fibromyalgia
- Small with nonsteroidal anti-inflammatory drugs (NSAIDs) in osteoarthritis and inflammatory arthritis

Website: https://effectivehealthcare.ahrq.gov/products/nonopioid-chronic-pain/research
Opioid Treatments for Chronic Pain

- Small improvements versus placebo in pain and function
- Increased risk of harms at short-term (1 to <6 months) follow-up
- Evidence on long-term effectiveness is very limited
- Evidence of increased risk of serious harms that appear to be dose dependent

Website: https://effectivehealthcare.ahrq.gov/products/opioids-chronic-pain/research
Opioids:

- Are probably less effective than NSAIDs for surgical dental pain and kidney stone pain
- Might be similarly effective to NSAIDs for low back pain
- Might be more effective than gabapentin for acute neuropathic pain
• Triptans, NSAIDs, antiemetics, dihydroergotamine, and acetaminophen improve pain and function with generally mild, transient adverse effects.

• Lasmiditan and gepants improve pain relief and are potentially lower risk than vasoactive medications in patients with cardiovascular risk factors.

• Insufficient evidence for opioids in treatment of episodic migraine.

Website: https://effectivehealthcare.ahrq.gov/products/migraine-treatments/research
Community Engagement
Understanding Pain and Pain Management

- Quality of evidence
- Balance Benefits/Harms
- Values & Preferences
Two Paths Toward Understanding

Public Comment – Broad

Individual Conversations – Deep

Better understanding
Management of Acute and Chronic Pain: Public Comments and Conversations

By soliciting comments and participating in conversations, CDC aimed to better understand public perspectives on and experiences with pain and pain management, especially as they relate to experiences...

Managing pain, including the benefits, risks, or harms of pain management options.

Choosing among pain management options, including factors like each option's accessibility, cost, benefits, or risks.

Getting information needed to make pain management decisions.

CDC sought to engage specifically with three key groups:

- Patients with acute or chronic pain
- Patients’ family members and caregivers
- Clinicians who care for patients with pain or conditions that can complicate pain management (e.g. opioid use disorder or overdose)
Community Engagement Timeline

**Apr 17 – June 16, 2020**
- **FRN 1**
  - Public Comment

**July 22 – Aug 21, 2020**
- **FRN 2**
  - Individual Conversations; Public Comment Analysis

**Sept 2020**
- Completed Individual Conversations

**Oct - Nov 2020**
- Individual Conversations Analysis

FRN = Federal Register Notice
FRN 1
Management of Acute and Chronic Pain: Request for Comment
The comment period remained open for 60 days (from April 17 – June 16, 2020) and received, on average, more than 88 comments per day, resulting in...

5,392 Total Comments

4,150 From Patients

702 From Advocates/Industry Groups

431 From Caregivers

109 From Clinicians
FRN 2
Management of Acute and Chronic Pain: Opportunity for Stakeholder Engagement
The invitation period remained open for 30 days (from July 22 – Aug. 21, 2020). There were 973 registrations.

106 Conversations

42 Patients  21 Caregivers  43 Clinicians
Fieldwork Overview

106 individual conversations

42 patients | 21 caregivers | 43 clinicians

- 14 mostly harmed by opioids
- 45 mostly helped by opioids
- 33 both harmed and helped
- 14 unknown impact or N/A

8 Northwest
28 Southwest
19 Midwest
21 Southeast
18 Northeast
1 Islands
11 Unknown
Insights of Key Themes

**Theme 1:** Achieving Reduced Opioid Use through Diverse Approaches
- Quality & Capacity: Delivering the Highest Standard of Care
- Strategy & Management: Tailoring Individualized Care
- Access & Availability: Overcoming Barriers to Care
- Oversight & Enforcement: The Impact of Criminalization
- Treatments & Therapies: Weighing the Risks and Benefits

**Theme 2:** Impact of Misapplication of the 2016 Guideline
- Communication & Awareness: How Information is Gathered and Exchanged
- Conditions & Constituencies: Adapting to Unique Challenges and Needs
- Perception & Discourse: Opportunities for Reframing the Conversation

**Theme 3:** Environment and Considerations Impacting Reception/Design
- Policy & Governance: The Influence on Attitudes and Action
- Opportunities & Requests: Stakeholder Suggestions for Change
- Psychology & Outlook: The Role of Perspective and Mental Health
- Relationships & Connection: Community Creates a Life Worth Living

**FRN 1**
Federal Advisory Committee Engagement (BSC/NCIPC)
On Dec. 4, 2019, the Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC) established the Opioid Workgroup (OWG) at CDC’s request.

The OWG reports to the BSC/NCIPC, a federal advisory committee.
The primary purpose of the OWG is to:

• Review the updated draft Guideline for opioid prescribing (as prepared by CDC);

• Provide independent, broad, external, transparent input on the diverse and complex issues involved in this effort; and

• Develop a report that will provide the workgroup’s findings and observations about the draft Guideline to the BSC/NCIPC.
CDC held a public nomination process for prospective OWG members from Dec. 4, 2019 through Feb. 4, 2020.

In seeking a balance of perspectives among prospective OWG members, CDC sought inclusion of audiences:

- Directly affected by the 2016 Guideline;
- Would be directly involved in implementing or integrating updated or expanded recommendations into current practice;
- Qualified to provide representation of a specific discipline, expertise, or viewpoints in alignment with the tasks of the OWG.
OWG Nomination and Selection Process

• 255 nominations received
• Curricula vitae reviewed
• List of prospective members created based on expertise and diversity in perspectives
• Invitations to participate sent
• Requested and reviewed nominees’ disclosures of competing conflicts of interest, if any
• OWG membership finalized
• Presented at July 22, 2020 BSC/NCIPC public meeting
The OWG has 23 Members

- Patients with pain, caregivers, and family members of patients with pain
- Clinicians and subject matter experts:
  - primary care
  - pain medicine
  - public health
  - behavioral health
  - pharmacy
  - emergency medicine
  - medical toxicology
  - obstetrics/gynecology
  - bioethics
  - orthopedic surgery
  - plastic surgery
  - dentistry
  - sickle cell disease
  - substance use disorder treatment
  - research
- 3 BSC/NCIPC members; OWG chair is an appointed BSC/NCIPC member
- Federal partners serve as ex-officio members
- Designated Federal Officer that is a subject matter expert from the NCIPC
The OWG had 11 virtual meetings from October 2020 through June 2021.

**Oct. 2020:** Review of the Terms of Reference and an orientation to workgroup operations

**Nov. 2020:** Review of the processes used to gain community perspectives and insights

**Feb. 2021:** Overview of Grading of Recommendations Assessment, Development, and Evaluation (GRADE)

**Mar. 2021:** Overview of the draft updated Guideline for opioid prescribing

**Apr. – Jun. 2021:** Review the draft updated Guideline and develop their report of findings and observations

The OWG report will be presented to the BSC/NCIPC at a public meeting on July 16, 2021.
Federal Partner Engagement
Federal partner engagement

Federal partners serve as ex-officio members of the OWG.

Representatives from the:
- National Institute on Drug Abuse (NIDA) at the National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Food and Drug Administration (FDA)
- Indian Health Service (IHS)
Federal Partner Engagement

The BSC/NCIPC includes ex-officio members from the:

- Administration for Children and Families
- Administration for Community Living
- Administration on Aging
- National Institute for Occupational Safety and Health and the National Center for Health Statistics at the CDC
- Health Resources and Services Administration
- Indian Health Service
- Food and Drug Administration
- Substance Abuse and Mental Health Services Administration
- National Institute on Aging, the National Institute of Child Health and Human Development, NIDA, and the National Institute of Mental Health at the NIH.

Federal partners will have the opportunity to review the full draft updated Guideline as part of Departmental clearance.
Upcoming Activities and Milestones
OWG report presented at July 16, 2021 BSC/NCIPC meeting.

- The BSC/NCIPC will then review the OWG’s report and provide recommendations for CDC to consider as part of the Guideline update process.
- CDC will revise the draft updated Guideline and obtain CDC and HHS clearance.
The draft updated Guideline will be posted in the Federal Register for a 60-day public comment period by the end of 2021.

Subject matter experts will independently conduct peer review of the draft updated Guideline concurrently during the public comment period.
In 2022, CDC will:

- Revise the draft updated Guideline considering public comments and peer review and obtain CDC/HHS clearance.
- Develop a suite of translation and communication resources to be co-released with the Guideline publication.

Release of a final updated Guideline is anticipated to occur in late 2022.
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.