

**Observations presented to the
National Center for Injury
Prevention and Control's
Board of Scientific Counselors**

**on behalf of the
Opioid Guideline Workgroup**

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Workgroup Chair

Workgroup Members

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- Katherine Galluzzi, DO
- Traci Green, PhD, MSc
- Mitchell Katz, MD
- Erin Krebs, MD MPH
- Gregory Terman, MD, PhD
- Mark Wallace, MD
- Designated Federal Official
 - Amy B. Peeples, MPA

Observations

- The role of the Workgroup was to provide observations about the:
 - Guidelines
 - Clinical evidence review
 - Contextual evidence review
- To the Board of Scientific Counselors
- Workgroup members met four times by teleconference (January 8, 13, 15, and 18)

Consultants to the Workgroup

Consultant Area	Participation
Pediatrics & Anesthesiology	<i>Ad hoc</i> , not contacted
Occupational Med & Worker's Comp	<i>Ad hoc</i> , not contacted
Obstetrics & Gynecology	Participated 1/15
GRADE methods & cost effectiveness	Participated 1/8, 1/13, & 1/15
Medical Ethics	<i>Ad hoc</i> , not contacted
Addiction Psychiatry	Participated 1/15
Physical Medicine & Rehabilitation	Participated 1/13
Family member affected by loss of a loved one to opioid overdose	Participated 1/13

Overall Observations

- Support *integrated care* for people with chronic pain
- Monitoring of Guideline implementation for evidence of impact and unintended consequences and modification when warranted

Overall Observations (2)

- Pediatric and adolescent populations should be considered for future updates
- Risks and benefits are areas of active research.
 - Contextual evidence review may need to be updated more frequently than the clinical evidence review
 - Encourage CDC to work with partners to support additional research

Overall Observations (3)

- Strong preference for Guideline Recommendations framed with positive language
- Cost feasibility data are lacking and subject to great variability.
 - More research is required

Overall Observations (4)

- Concerns about access, cost, and insurance coverage
 - GR #1, #6, #7, #8, #9, #10, & #12.
- Systematic changes in payment policies will likely be required to support implementation
- Encourage CDC to work with federal partners to support congruent payment policies

Overall Observations (5)

- Routine patient education throughout therapy
 - Safe storage and disposal
 - Risks and benefits
 - Treatment goals
 - Mental health
 - Pain and function

Overall Observations (6)

- Primary care providers may require additional education on approaches integral to implementation of the Guidelines
 - non-pharmacologic and integrated care,
 - offering naloxone to patients with chronic pain,
 - medication assisted treatment for opioid use disorder.
- Encourage CDC to work with partners to support and/or provide appropriate education.

Observations About Specific Guideline Recommendation Statements

Guideline Recommendation #1

- All members of the Workgroup agreed with the type and category of evidence for Guideline Recommendation #1.
- Commend the ordering of statements
- Clear wording of good messages
 - Opioids not routine therapy
 - Pain and function are important

Guideline Recommendation #1

- Concerns about access to care, particularly for non-pharmacologic therapies
- Suggest clear preference for integrated care throughout the Guidelines

Guideline Recommendation #2:

- All members of the Workgroup agreed with the type and category of evidence for Guideline Recommendation #2.

Guideline Recommendation #2:

- Commend focus on patient-centered goals for improvement of pain and/or function
- Some concern that some providers would interpret the phrasing of “pain and function” to mean that improvements were required in both pain and physical function in order to justify continuation of opioid therapy.

Guideline Recommendation #2:

- Mental health concerns
- Encourage addition of language to include evaluation of mood in addition to pain and function.

Guideline Recommendation #3

- All members of the Workgroup agreed with the type and category of evidence for Guideline Recommendation #3.
- Safety discussions should occur at initiation and continue throughout opioid therapy.

Guideline Recommendation #3

- Information about safe disposal of medication should be included in the tools accompanying the Guidelines.
- Possible risk to household members included in the discussion of risks and benefits with the patient

Guideline Recommendation #4

- All members of the Workgroup agreed with the type and category of evidence for Guideline Recommendation #4.
- Guideline Recommendation #4 is evidence type 4.
- Consistent with best practices and well-deserves Category A designation.

Guideline Recommendation #5

- Significant discussion about content, category, and evidence type
 - Six of the nine Workgroup members agreed with the category A and evidence type 3 designation.
 - Three felt that the evidence type 3 was appropriate except for the last paragraph of supporting text
 - Category A and evidence type 3 appropriate if discussion of tapering removed from supporting text
 - Two Workgroup members suggested revisions

Guideline Recommendation #5

- Last paragraph of the supporting text does not directly support Guideline Recommendation #5.
- Virtually no studies of long-term benefits or improvement in pain and function with opioid therapy
- Encourage future studies to fill this data gap.

Guideline Recommendation #5

- One member strongly opposes Guideline Recommendation #5 as it is written.
- This member stated repeatedly that the current recommendation clearly suggesting dose limits is not supported by any data showing a decrease in benefit/risk ratio at these arbitrary numbers.
- This member expresses concern that the current wording of Guideline Recommendation #5 will undermine support for the entire Guidelines from providers and professional organizations.

Guideline Recommendation #5

- Focus on patient pain and function missing
- Pain or functional improvement should be the impetus for any change in dose

Guideline Recommendation #6

- All members of the Workgroup agreed with the evidence type for Guideline Recommendation #6.
- Considerable discussion about the Category
 - One member considers this Category B
 - Many members support Category A designation only if the statement includes a range for duration

Guideline Recommendation #6

- Many members felt that three days was too limited and preferred a range of values
 - Seven days or fewer : 4 members
 - 3–7 days: 2 members
 - 5–7 days: 1 member
 - 3–5 days: 1 member
 - One member was strongly opposed to seven days as “too long”.

Guideline Recommendation #6

- Specific wording suggestion
 - “Avoid prescribing more than three days supply, unless circumstances clearly warrant additional opioid therapy.”
- Safe medication storage and disposal

Guideline Recommendation #7

- All members of the Workgroup agreed with the type and category of evidence for Guideline Recommendation #7.
- Should apply to all patients
 - Several expressed concern that the wording included only opioid naïve patients.

Guideline Recommendation #7

- Individual members suggested specific edits
- Implies all patients should be at a dose of zero opioids
- Fails to suggest what else providers should do besides eliminating opioids

Guideline Recommendation #8

- All members of the Workgroup agreed with the type and category of evidence for Guideline Recommendation #8.
- Stronger by including depressants or sedatives among the risk factors: 2 members

Guideline Recommendation #9

- All members of the Workgroup agreed with the type and category of evidence for Guideline Recommendation #9.
- Should apply high doses and dangerous combinations, not just multiple provider situations

Guideline Recommendation #9

- PDMP access and utility varies
- Data sharing for border areas
- Encourage CDC and federal partners to support PDMP development and operation
- Efficient data access and interfaces

Guideline Recommendation #10

- All members of the Workgroup agreed with the evidence type for Guideline Recommendation #10.
- Majority supported Category A rather than B
- Universal recommendation
 - More focused on patient safety
 - Less likely to increase stigma

Guideline Recommendation #10

- Encourage use of simplest appropriate test
 - Reduce cost
 - Improve feasibility
- Educate providers about test interpretation
- Research on risks and benefits of urine drug testing is limited

Guideline Recommendation #11

- All members of the Workgroup agreed with the type and category of evidence for Guideline Recommendation #11.
- Risk mitigation with co-prescription

Guideline Recommendation #11

- Current language
 - Presumes appropriate benzodiazepine
 - Fails to encourage patient-centered decision making about risks and benefits
- Supporting text
 - Importance of pharmacist on care team
 - Use of PDMP to identify concurrence

Guideline Recommendation #11

- Workgroup members noted that the wording of Guideline Recommendation #11 has changed significantly during the comment and review process.
- Several preferred original wording
- Discussion about AVOID vs USE CAUTION
 - Several supported AVOID, two strongly

Guideline Recommendation #12

- Disagreement for Category
 - One member strongly for Category B
 - Remaining members Category A
- Suggest evidence type upgrade 3 to 2
- Commend the wording
 - Encourage proactive treatment
 - Expand buprenorphine prescribing

Review of Supplemental Materials: Clinical Evidence Review, Contextual Evidence Review, and Comments from Stakeholders, Peer-Reviewers, and the Public

Review of Supplemental Materials

- Clinical Evidence Review well-done
- Continued support for future clinical and contextual research on benefits and risks of opioid therapy for chronic pain.
- Future Contextual Evidence Review should seek out specific non-pharmacologic therapies

Review of Supplemental Materials

- Mood should be evaluated with pain and function (GR#2 & GR#5)
- Breadth and variety of positions on the issue of opioid therapy for chronic pain among adults managed in primary care.
- Comments suggest guidelines are needed

Review of Supplemental Materials

- Desire that patient-centered care is enhanced rather than reduced by these Guidelines
- Members felt that the guidelines could be implemented in a manner consistent with patient-centered care