



## **Update: How the CDC Guidelines Are Impacting Patient Care**

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### **Disclosures**

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- Nothing to disclose

## Learning Objectives

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- Describe the opioid prescribing guideline created by the CDC (12 recommendations)
- Discuss the impact that the guideline could have on the misuse and abuse of prescription drugs and unintentional OD
- Discuss the impact that the guideline could have on the treatment of pain



## Prelim Comments

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- Difficult times, difficult subject
- Simplistic treatment by media vs references at end
- Media can influence (whether or not a Russian troll)
- Unfair blame (Dasgupta et al; Schatman & Ziegler)
- Bring multiple perspectives (90% is only 10%)
- Palliative care, pain and symptom management
- Positive patient outcomes



## Prelim Comments (cont'd)

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- Rx guidelines can be helpful
- Can be challenging to create
- But substantive and procedural concerns with CDC Guideline
  - Drafters
  - “Participants”
  - Gospel
- CARA: A better example

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## Mission of the Centers for Disease Control and Prevention (CDC)

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- CDC's A-Z Index: “topics with relevance to a broad cross-section of CDC.gov's audiences. The items are representative of popular topics, frequent inquiries, or have critical importance to CDC's public health mission.”
- Overdose?
- Pain? No mention

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## The CDC Prescribing Guideline is . . .

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- Accessible via Injury Prevention & Control (for pain treatment?)

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## Voluntary

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- “The recommendations in the guideline are voluntary, rather than prescriptive standards.
- They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations.
- Clinicians should consider the circumstances and unique needs of each patient when providing care.”

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## CDC's Core Expert Group

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## **CDC's "Public" Webinar: "What a difference a day makes, 24 little hours"**

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## **The CDC, WLF, and Violations of the Federal Advisory Committee Act**

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## CDC's Open Comment Period: "It's beginning to look a lot like Christmas"

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- December 14, 2015 through January 13, 2016
- Number of comments received (remember the webinar)?

▪4,373



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## CDC's Final Rx Guidelines Released

March 15, 2016

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Posted on their website  
(along with a broken link)

## Quality/Strength of Evidence Supporting Rec

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- Type 1 evidence: Randomized clinical trials/overwhelming evidence from observational studies.
- Type 2 evidence: Randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies.
- Type 3 evidence: Observational studies or randomized clinical trials with notable limitations.
- Type 4 evidence: Clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations.

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## The 12 Recommendations

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- Of the 12 Recs, how many were supported by high quality/strong evidence (Type I)?
- NONE
- 11 out of 12 had weak evidence to support the recommendation (evidence Type 3 or 4/weak, very weak)
- But Type 2 evidence = Rec#12: Clinicians should offer or arrange evidence-based treatment for patients with opioid use disorder
- Summary follows (see specifics: <http://bit.ly/2dsxtCz>)

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## Recommendations 1-4

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- #1: Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain
- #2: Before starting, establish Tx goals, and should consider how it will be discontinued if risk outweighs benefits. Continue only if clinically meaningful improvement in pain AND function
- #3: Before starting and during opioid therapy, should discuss known risks opioid therapy with Pts [but NSAIDs carry risks too]
- #4: Should Rx immediate release instead of ER/LA opioids

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## Recommendations 5-6

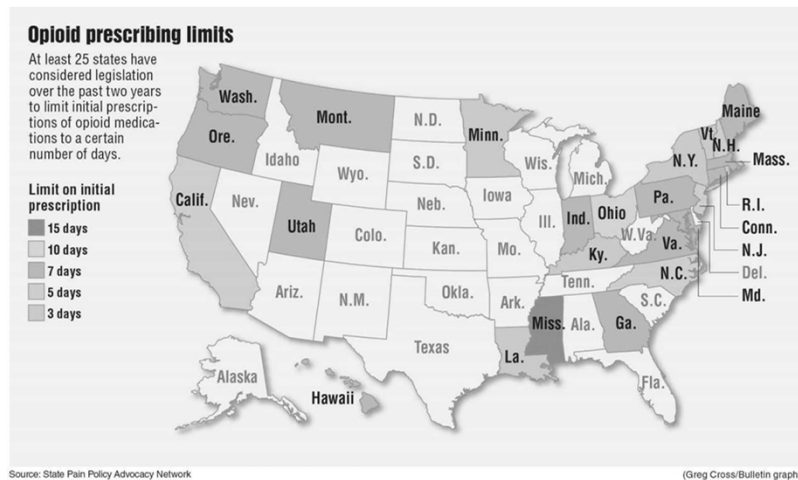
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- #5: When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to  $\geq 50$  morphine milligram equivalents (MME)/day, and should avoid increasing dosage to  $\geq 90$  MME/day or carefully justify a decision to titrate dosage to  $\geq 90$  MME/day.
- #6: When Rx for acute pain, Rx lowest effective dose of IR. 3 days or less will often be sufficient; more than 7 days will rarely be needed
  - Very weak evidence
  - I thought this was about chronic pain?
  - Leftover meds legit concern
  - Partial fill legislation holds promise

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## Acute Pain: Potential Opioid Prescribing Limits

(Reprinted with permission of publisher)



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## Recommendations 7-10

- #7: Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.
- #8: Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages ( $\geq 50$  MME/day), or concurrent benzodiazepine use, are present.
- #9: Use your state PDMP
- #10: Use UDT before starting and consider at least once annually

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## Recommendations 11-12

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- #11: Avoid co-prescribing pain meds and benzodiazepines whenever possible
- #12: 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. (Strong evidence, 2)

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## Multiple Impacts

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- Rx has decreased prior to guidelines, OD rate continues to climb, most ODs stem from illicit and polypharm based
- Unquestioning reliance, treated as gospel
- Race to the bottom (see, MSR for MSR)
- Insurance companies
- Investigations of prescribers for not following
- De facto standard

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## Multiple Impacts

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- Involuntary tapering (not because of individual risk; unilateral or state-mandated)
- Deborah Dowell (MD) & Tamara Haegerich (PhD), of the CDC: “neither this review nor CDC's guideline provides support for involuntary or precipitous tapering.”
- “Such practice could be associated with withdrawal symptoms, damage to the clinician–patient relationship,
- and patients obtaining opioids from other sources.”
- “Clinicians have a responsibility to carefully manage opioid therapy and not abandon patients in chronic pain. Obtaining patient buy-in before tapering is a critical” (Dowell & Haegerich, 2017).

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## Multiple Impacts

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- Suicide
- Increased pain
- Opting out by clinicians
- Warnings to clinicians from group practice
- Guidelines become de facto rules without proper administrative procedure
- Pharmacists not fill
- No clarification by CDC, no expressed intent to revise

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## Multiple Impacts (cont'd)

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- Petition to the FDA by PROP:
  - Immediate removal of ultra-high dosage unit (UHDU) oral and transmucosal analgesics from the market
  - Ultra-high dosage defined by petitioners: dosage above 90 MEDD
  - In Maine, estimated >16K patients at or above 100 MEDD
  - <https://www.regulations.gov/document?D=FDA-2017-P-5396-0001>
- CMS proposed changes: Cap at 90 MED, 2019 Medicare Part D, prescription drug program
- “Any prescription at or above that level would trigger a ‘hard edit’ requiring pharmacists to talk with the insurer and doctor about the appropriateness of the dose. . . . The trigger can only be overridden by the plan sponsor after efforts to consult with the prescribing physician” (Anson, 2018)

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## Multiple Impacts (cont'd)

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- Stefan Kertesz, MD (pain and addiction specialist):  
“If this CMS proposal is adopted, it will accelerate an ongoing pattern of involuntary opioid tapers . . .
- I have great concern for today’s high dose patients, many of whom have complex disabilities. Their disabilities often reflect a combination of underlying physical disease, mental conditions, harm from the health care system and opioid dependence, even if those same opioids confer some degree of relief. Over the last year, I have received wave after wave of reports of traumatized patients, with outcomes that include [:]
- Suicidal ideation, medical deterioration, rupture of the primary care relationship, overdose to licit or illicit substances, and often enough, suicide.” (quoted in Anson, 2018)

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## Summary

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- Road to hell?
- Rx was already in decline before CDC guideline
  - Most OD deaths in MA caused by illegal drugs (8.3% had an Rx; 85% heroin or fentanyl)
- Mess
- Tyranny of the minority?
- Pendulum to the other extreme
- Knee-jerk reaction
- ODs continue, illicit and polypharm are drivers—not legit treatment of pain
- The *Just Say No* program is alive and well
- Blaming all prescribers = arresting wrong suspect

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## Summary (cont'd)

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- Impact on patient care? Misinterpretation, opting out, involuntary tapering, suffering, suicide (April 15, VA)
- Hope? CARA (Comprehensive Addiction & Recover Act) (2016):
- Sec. 101 – Development of Best Practices for Prescribing of Prescription Opioids: This section requires the establishment of an inter-agency task force, composed of representatives from HHS, VA, DEA, CDC, and other federal agencies, as well as addiction treatment organizations and other stakeholder communities to develop best practices for pain management and pain medication prescribing (practicing physicians, pharmacists, patient groups, etc)
- Hope, part II. Trickle has started (admits:illicit, double-count; Other side of Opioids; Reimbursement issues; common ground)

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## Thank you for improving people's lives

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- Special thanks to the following panelists who contributed to the first PAINWeek panel in 2016 on the CDC Guidelines: Jennifer Bolen, JD; Jeff Fudin, PharmD; and Steven Stanos, DO.

