Update: How the CDC Guidelines Are Impacting Patient Care

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Disclosures

- Nothing to disclose

Learning Objectives

- 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

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Current climate

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Where am I?

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Prelim Comments

- 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)

- 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 . . .

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

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Voluntary . . .

- "The recommendations in the guideline are voluntary, rather than prescriptive standards. . . . 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"

- 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

Posted on their website

(along with a broken link)

Quality/Strength of Evidence Supporting Rec

- 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

- 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

- #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.
- #3: Before and during opioid therapy, should discuss known risks of opioid therapy [but NSAIDs carry risks too]
- #4: Should Rx immediate release instead of ER/LA opioids

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Recommendations 5-6

- #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 ≥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.
- #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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Recommendations 7-10

- #7: Clinicians should evaluate benefits and harms of continued therapy . . . 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 (≥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

- #11: Avoid co-prescribing pain meds and benzodiazepines
- #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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Gospel, cut and paste?

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Involuntary tapering

- #7: Clinicians should evaluate benefits and harms of continued therapy . . . 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.
- How define?
- Not based on individual risk
- Government mandate
  - VA
  - Maine

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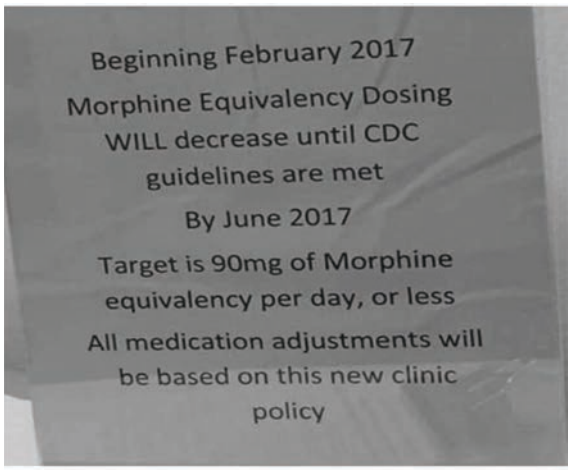
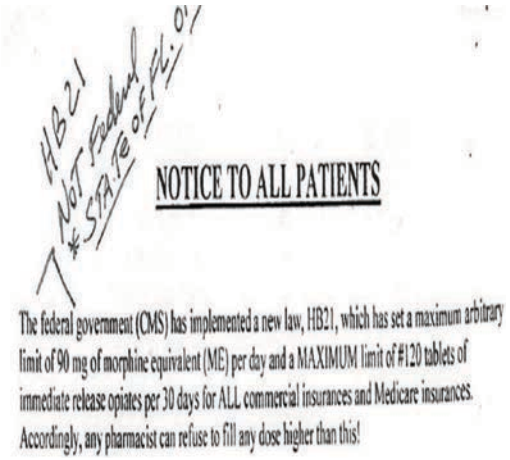
Misinterpretation





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Involuntary tapers, a recent survey respondent

- "My wife went from being on a dose of 120 [MED] a day to 10
- "Then none within two months"
- "Doc said: it's not up to me, it's up to the CDC and the FDA [and] I won't lose my license because of your wife's pain"
- She committed suicide ("She died by her own hand")
  - https://twitter.com/tal7291/status/998558947828101120

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Does the CDC support involuntary tapers?

- "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."
  - Deborah Dowell, MD, MPH & Tamara M. Haegerich, PhD of the CDC
    - "Changing the Conversation About Opioid Tapering," *Annals of Internal Medicine*, 167 (3), August 2017
- "Disclaimer: The conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention."

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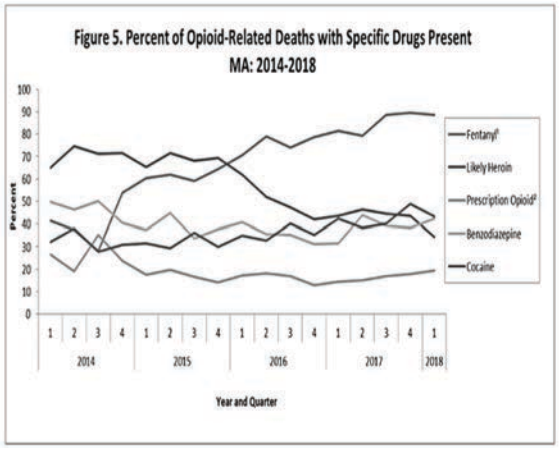
OD's from Illicit Opioids



"The increased risk of death related to fentanyl is what's driving this epidemic."
Dr. Monica Bharel, Mass. Public Health Commissioner

The presence of fentanyl continues to rise, now a factor in nearly 90 percent of deaths

FOR IMMEDIATE RELEASE:
8/24/2018 Department of Public Health

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Multiple Impacts

- Rx has decreased prior to guidelines, OD rate continues to climb, most ODs stem from illicit and polypharm based
- Intentional or unintentional ODs?
- Race to the bottom (see, MSR for MSR)
- Insurance companies & Investigations of prescribers for not following
- De facto standard

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Opting out, abandonment, and no Govt plan

Chronic pain patients struggle after Beachwood doctor suspended

Updated 5:04 AM; Posted 5:00 AM

Patients of Beachwood pain doctor Jerome Yokiel say they've struggled to gain access to their complete medical records and to find other doctors willing to treat them since Yokiel's license was temporarily suspended last year. They say they feel "blacklisted" by many area doctors, who don't want to treat Yokiel's patients, many of whom have complex medical issues. John Tramsak, of Bedford, shown here at his home in June, could no longer mow the lawn or care for a relative in the months after losing his pain doctor. (Chuck Crow, The Plain Dealer)

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Multiple Impacts

- Warnings to clinicians from group practice
- Guidelines become de facto rules without proper administrative procedure
- Pharmacists not fill
- No clarification by CDC

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Multiple Impacts (cont'd)

- 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)

- Stefan Kertesz, MD (pain and addiction specialist):
  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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Positive impacts?

- Unintended negative impacts concern
- Foreseeability (Merton)
- Any positive?
- Tapering, when clinically indicated and proper support
- Recognition of need for Safe + effective + reimbursement of alternatives

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Summary

- Road to hell?
- Rx was already in decline before CDC guideline
- ODs continue, illicit and poly-pharm are drivers—not legit treatment of pain
- What happened to individualized care?
- Blaming all prescribers = arresting wrong suspect?
- Need for accurate data to inform policy, not hysteria (but bounded rationality)

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Hope

- CARA (Comprehensive Addiction & Recover Act) (2016):
- More seats at the table, more need for humility
  - 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)

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Hope #2: CDC Mea culpa

- "it is important to differentiate the deaths to craft appropriate prevention and response efforts."
- "Unfortunately, disentangling these deaths is challenging because multiple drugs are often involved"
- "Additionally, death certificate data do not specify whether the drugs were pharmaceutically manufactured and prescribed by a health care provider, pharmaceutically manufactured but not prescribed to the person (i.e., diverted prescriptions), or illicitly manufactured."

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Hope #2: CDC Mea culpa

- "estimating prescription opioid–involved deaths with the inclusion of synthetic opioid–involved deaths could significantly inflate estimates."
- "With the traditional method, an estimated 32 445 prescription opioid–involved deaths occurred in 2016. With the more conservative method, 17 087 prescription opioid–involved deaths occurred in 2016"
- "A new, more conservative estimation of prescription opioid–involved deaths is proposed to better differentiate deaths involving prescription (pharmaceutically manufactured) opioids from deaths involving illicit opioids (heroin, IMF)." (Seth et. al, April 2018)

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Media trickle continues about unintended + alternatives discussion

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Thank you for improving people's lives

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