Update: How the CDC Guidelines Are Impacting Patient Care

Stephen J. Ziegler, PhD, JD

Disclosures

- Drug & Health Policy Consulting, LLC
  - CEO
- Advisory Board: Nebraska Hemp Association

Learning Objectives

- Describe the opioid prescribing guideline and its history, highlighting the more controversial recommendations (slides are available);
- Discuss the impact of the guideline on:
  - 1) Pain treatment
  - 2) Patients
  - 3) Healthcare professionals
  - 4) Unintentional OD
- Describe the contents of the HHS Draft Report on Pain Management Best Practices

Current climate

PainWeek.

Where am I?

PainWeek.

Prelim Comments

- Guidelines can be helpful & challenging
- Concerns with CDC Guideline:
  - Process/procedure
  - Substance (impacted by above)
  - Bias, negative impacts, lack of updates
- CARA: Positive example & step
  - HHS Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations

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2013 (3 years before CDC Guideline)

- "opioid dosing and duration guidelines that focus primarily on higher dose use may not be sufficient to achieve a substantial reduction in morbidity related to prescription opioid use."
  - Fulton-Kehoe D, Garg RK, Turner JA, Bauer AM, Sullivan MD, Wickizer TM, Franklin GM. Opioid poisonings and opioid adverse effects in workers in Washington State. Am J Ind Med. 2013;56:1452-1462. [One of the above authors was a member of the Guideline's Core Expert Group]

CDC's Core Expert Group

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

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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"

- Dec 14, 2015 through Jan 13, 2016: 4,373 comments
- 30 days during the holidays vs 24 hours

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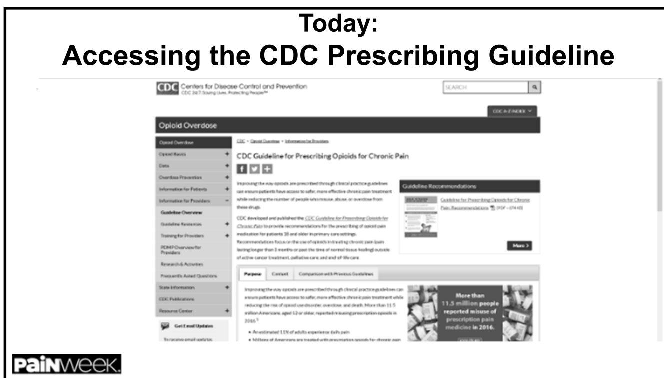
March 15, 2016. Guideline published

- Resources for prescribers: Click here
- ERROR: PAGE NOT FOUND

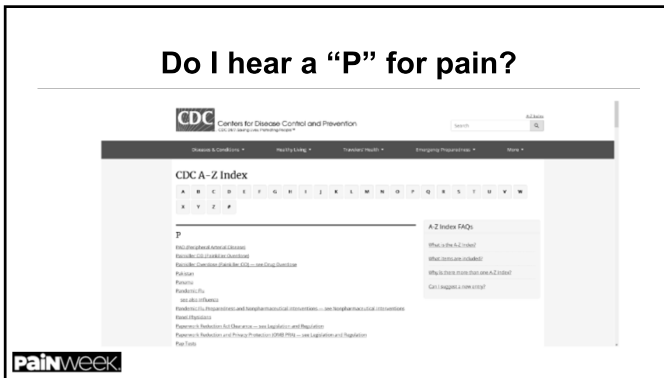
Today: Accessing the CDC Prescribing Guideline



A-Z Index at the top right

- “The items are representative of popular topics, frequent inquiries, or have critical importance to CDC’s public health mission.”
- Does the chronic pain that impacts millions have critical importance to the CDC?

Do I hear a "P" for pain?



Is the guideline 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."

Recommendations 1-4

- #1: Nonpharmacologic therapy and nonopioid 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

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
  - I thought this was about chronic pain?
  - Leftover meds legit concern

Recommendations 7-10

- #7: To be discussed soon . . .
- #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

Recommendations 11-12

- #11: Avoid co-prescribing pain meds and benzodiazepines
- #12: Clinicians should offer or arrange evidence based treatment . . . for patients with opioid use disorder. (Strong evidence to support recommendation, 2)

PAINWEEK.

Gospel, cut and paste?

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Misinterpretation

Beginning February 2017
Morphine Equivalency Dosing
WILL decrease until CDC
guidelines are met
By June 2017
Target is 90mg of Morphine
equivalency per day, or less
All medication adjustments will
be based on this new clinic
policy

HB21
Not Federal
* STATE of FL

NOTICE TO ALL PATIENTS

The federal government (CMS) has implemented a new law, HB21, which has set a maximum arbitrary limit of 90 mg of morphine equivalent (ME) per day and a MAXIMUM limit of #120 tablets of immediate release opiates per 30 days for ALL commercial insurances and Medicare insurances. Accordingly, any pharmacist can refuse to fill any dose higher than this!

PAINWEEK.

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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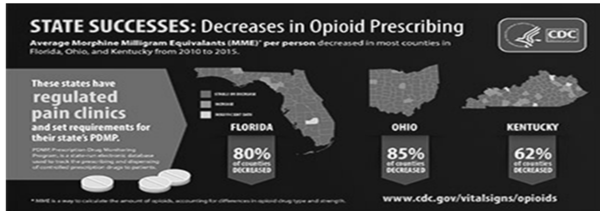
Decreases in Rx, but does that=success?



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Comparison: 3 Years Before vs 3 Years After Guideline

- 3 YEARS BEFORE the Guideline: "opioid dosing and duration guidelines that focus primarily on higher dose use may not be sufficient to achieve a substantial reduction in morbidity related to prescription opioid use." Fulton-Kehoe D et al. Am J Ind Med. 2013;56:1452-1462.
- 3 Years AFTER the Guideline: "Prevention of prescription opioid misuse alone is projected to have a modest effect on lowering opioid overdose deaths in the near future, and multipronged approach is needed to dramatically change the course of the epidemic." Chen et al. JAMA. 2019.

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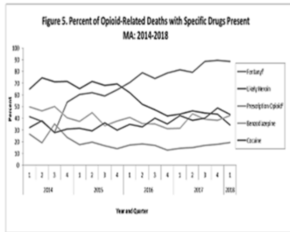
ODs from Illicit Opioids



"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

CDC Mea culpa in 2018 (2 years later)

- "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."

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)

If illicit opioids are drivers of OD, do some still blame prescribers?

- The value of data conflation;
- When more is learned, treat hypotheses like evidence.
- Ignore the complexity
- Contrary to a popular narrative, the National Institute of Drug Abuse (NIDA) recognized:

  Heroin use is rare in prescription drug users
- While prescription opioid abuse is a growing risk factor for starting heroin use, only a small fraction of people [~4%] who abuse pain relievers switch to heroin use. . . . This suggests that prescription opioid abuse is just one factor in the pathway to heroin. Furthermore, analyses suggest that those who transition to heroin use tend to be frequent users of multiple substances (polydrug users).
- Additional analyses are needed to better characterize the population that abuses prescription opioids who transition to heroin use, including demographic criteria, what other drugs they use, and whether or not they are injection drug users. https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/heroin-use-rare-in-prescription-drug-users
  - (citing Jones et al., 2015; Muhuri PK, et al. (2013))

PaiNweek

Instead of just blaming opioids…

- How about <u>also</u> focusing on what leads people to abuse them in the first place? Understanding the social determinants of health
  - See, e.g., Dasgupta, Beletsky, & Ciccarone (2018).

PaiNweek

If reducing Rx and other interventions will only have a modest effect (at best), what does the DEA do?

- **Issue a Mea culpa like the CDC?**
- **Admit that the war on drugs is ineffective?**
- **Not exactly.**

PaiNweek

DEA United States Drug Enforcement Administration

Who We Are | What We Do | Resources | Search

Home / Press Releases / 2018 / 08 / 16 / Justice Department, DEA propose significant opioid manufacturing reduction in 2019

Drug Enforcement Administration

FOR IMMEDIATE RELEASE

Justice Department, DEA propose significant opioid manufacturing reduction in 2019

WASHINGTON – The Department of Justice and U.S. Drug Enforcement Administration have proposed a reduction for controlled substances that may be manufactured in the U.S. next year. Consistent with President Trump's "Safe Prescribing Plan" that seeks to "cut nationwide opioid prescription fills by one-third within three years," the proposal decreases manufacturing quotas for the six most frequently misused opioids for 2019 by an average ten percent as compared to the 2018 amount. The Notice of Proposed Rulemaking marks the third straight year of proposed reductions, which help reduce the amount of drugs potentially diverted for trafficking and used to facilitate addiction.

On July 11, 2018, the Justice Department announced that DEA was issuing a final rule amending its regulations to improve the agency's ability to consider the likelihood of whether a drug can be diverted for abuse when it sets annual opioid production limits. The final rule also promotes greater involvement from state attorneys general, and today's proposed reduction will be sent to those offices.

In setting the aggregate production quota, DEA considers data from many sources, including estimates of the legitimate medical need from the Food and Drug Administration; estimates of retail consumption based on prescriptions dispensed; manufacturers' disposition history and forecasts; data from DEA's own internal system for tracking controlled substance transactions; and past quota

PAINWEEK

Involuntary tapering?

- Recommendation #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.
- What = involuntary tapering?
  - Not based on individual risk
- Government mandate
  - VA
  - Maine
  - Oregon

PAINWEEK

Guideline being used as a standard by the DEA?

- "CDC Guideline as a red line for prescribing" (HRW)
- "Twelve physicians told Human Rights Watch that they had made involuntary dose reductions for patients—sometimes hundreds—who were compliant with screening procedures and appeared to be benefiting from their medication. This practice is inconsistent with the Guideline's recommendations, unsafe, and can severely undermine a patient's quality of life."

PAINWEEK

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
  - https://twitter.com/tal7291/status/998558947828101120

Does the CDC support involuntary tapers?

- 2017 (post guideline): "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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Multiple Impacts

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

Positive Impacts?

- Tapering, when clinically indicated and proper support
- Study by HRW & recommendations:
  - Limiting the unintended consequences of the response to the overdose crisis for chronic pain patients;
  - Ensuring continuity of care for patients of shuttered pain clinics;
  - Improving availability, accessibility, and affordability of multimodal pain management, including to nonpharmacological modalities; and
  - Improving data collection on the overdose crisis.

Hope: Media recognizing role of ILLICIT opioids, impacts on patients and HCPs

Hope: CARA

- CARA (Comprehensive Addiction & Recover Act) (2016):
- More seats at the table (and more balanced)
- The Task Force: "29 experts who have significant experience across the disciplines of pain management, patient advocacy, substance use disorders, mental health, and minority health." https://bit.ly/2EUKGlm

Hope: Draft Report on PM Best Practices

- Balanced pain management; a biopsychosocial model of care
- Individualized, patient-centered care [ONE SIZE DOES NOT FIT MOST]
- Ensure better and safer opioid stewardship through risk assessment based on patients' medical, social, and family history to ensure safe and appropriate prescribing
- Multidisciplinary approach to chronic pain that focuses on the patient's medical condition

Hope: Draft Report on PM Best Practices (cont'd)

- Addressing drug shortages that might affect acute and chronic pain care
- Improved healthcare coverage
- Reduction of stigma
- Education . . . Promoting therapeutic alliances b/w patients and providers.
- Innovative solutions to pain management such as telemedicine . . .
- Research. See, https://bit.ly/2EUKGlm

Summary

- CDC Guideline: Process and substance
- Transparency is foundation of open democracy
- Guideline revision and impact on patients and HCPs
- ODs continue, illicit and poly-pharm are drivers
- Blaming all prescribers = arresting wrong suspect
- Need for accurate data, not hysteria or hubris, to inform and influence policy

Difficult time—but thank you for helping to improve people's lives

- Contact information
- Stephen J. Ziegler, PhD, JD
- Purdue University, Professor Emeritus
- Sziegler@purdue.edu

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