If 6 were 9:  
The CDC’s Opioid Prescribing Guideline and the Veil of Secrecy

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Disclosures

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    • Balanced policies
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

Prelim Comments: Regulation of Medical Practice
Clinical Guidelines

- Original purpose: Support clinical decision making & combo knowledge + experience
- Challenges & revisions
- Today: Expanded use (insurance, potential standards, policy)
- CDC Concerns: Process, substance, intrusion, and Gospel
- Hope: Comprehensive Abuse & Recovery Act (CARA – step in right direction)

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

- “to protect America from health [and] safety . . . threats . . . Whether diseases . . . are chronic or acute . . . CDC fights disease and supports communities and citizens to do the same.”
- 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.”
So, what is of “critical importance” to CDC?

Increases in overdose (But Poly-pharm & Substance)

Drug overdose death rates in the United States have never been higher

- Drug overdose death rates have risen steadily in the United States since 1970. (See Figure 1)
- In 2007, 27,658 unintentional drug overdose deaths occurred in the United States.
- Drug overdose deaths were second only to motor vehicle crash deaths among leading causes of unintentional injury death in 2007 in the United States.
- Rates have increased roughly five-fold since 1990.
- Age-adjusted rates of drug overdose death for whites have exceeded those among African Americans since 2003.

![Figure 1: Rates of unintentional drug overdose death in the United States, 1970-2007](source: National Vital Statistics System)
What does NOT “have critical importance to the CDC’s public health mission” in A-Z?

PAIN

The CDC Prescribing Guideline is . . .

- Accessible via Injury Prevention & Control (for pain treatment?)
- “The recommendations in the guideline are voluntary”
- Does that mean HCPs should ignore them?
- NO

- NOT MANDATORY
CDC’s Core Expert Group
CDC’s “Public” Webinar:
Brought to you by the CIA and the musical genius of Renee Olstead

- “What a difference a day makes, 24 little hours”

Leaked Document: Core Expert Group

- Health researchers, state regulators, addiction treatment
- Gary Franklin, MD & Jane Ballantyne, MD
- Both of PROP (sought 100 MEDD re-label & Paulozzi LTR HD @ x)
- Funded by Phoenix House
- Who was not on the table (but on menu)?
- Active prescribers (Non-physician or active PM physicians)
- Pharmacists
- Patients
- FDA
The CDC, WLF, and Violations of the Federal Advisory Committee Act

WLF et al: Government must be open

- Govt agency
- Core Expert Group = Adv Comm subject to Fed Adv Comm Act
- Open meetings, release documents, prepare & release minutes
- Serious COI
- Sought to evade APA and open comment
- Quack Quack
- Intent to be adopted
- Congress involved
CDC’s Open Comment Period:  
“Its beginning to look a lot like Christmas”

- December 14, 2015-January 13, 2016
- Number of comments received (remember the webinar)?
  - 4,373

CDC’s Final Rx Guidelines Released
March 15, 2016

Posted on their website
Meet the new boss, same as the old boss
...with Limited Support
March 15, 2016

Summary of Rx Guideline

- 12 Recommendations (outside of active cancer, palliative, EOL)
- Each recommendation contained two additional categories:
  - I) WHO it applied to (A): 11/12; (B) N/A all: Rec #10 was Category (B): UDT
  - II) QUALITY/Strength of Evidence to support the Rec based on literature reviewed (Types 1-4); with 1 = Very strong, 4 = very weak evidence:
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.

Methodological Concerns: Insufficient Body of Evidence re Effectiveness of Opioid Therapy?

**Exclusion Criteria**

- Absence of evidence not =
- Tayeb et al (2016)
- Analgesic trials 1 YR or less excluded
- Problem: Vast majority 12 weeks or less
- Ethics & harm concerns
- If applied same Min threshold, None of major non-opioid therapies would get Rec
The 12 Recommendations

- Of the 12 Recs, how many were supported by high quality/strong evidence (Type I)?
- NONE
- But Type 2 = Rec#12: Clinicians should offer or arrange evidence-based treatment for patients with opioid use disorder
- AKA: 11 out of 12 had weak evidence to support the recommendation (Evidence Type 3 or 4=weak, very weak)
- Are they all bad? Yes and no.

Recommendation #1: Weak evidence [3]

- Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain.
- Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient.
- If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
- 2-2? Reimbursement? But non-opioids could be dangerous?
Rec #2: Very Weak Evidence [4]

- Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

- Two for two?

Rec #3: Weak Evidence [3]

- Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

- Suggesting a higher standard when opioids are Rx?
Rec #4: Very Weak Evidence [4]

- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended release/long-acting (ER/LA) opioids.

Rec #5: Weak Evidence [3]

- 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.

- Dosage triggers, ceilings, and morphine equivalency.
  - See, Ziegler SJ. The proliferation of dosage thresholds in opioid prescribing policies and their potential to increase pain and opioid-related mortality. Pain Med, 2015; 16 (10), 1851–1856.
Rec #6: Very Weak Evidence [4]

- Long term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than 7 days will rarely be needed.
  
- Consider two stories: 3 days for a broken arm and 100 pills for knee surgery
  
- Partial fill legislation holds promise.

Rec #7: Very Weak Evidence [4]

- Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. 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.
Rec #8: Very Weak Evidence [4]

- Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid related harms. 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.

Rec #9: Very Weak Evidence [4]

- Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
- Have you run yourself?
Rec #10: Very Weak Evidence [4]

- One and only Category B (Rec not apply to all Pts)
- When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
- Okay, but UDTs have their own issues

Rec #11: Weak Evidence [3]

- Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
- Surprising Rec only gets a Type 3
- Holy Trinity
- Alcohol too
Rec #12: Strong Evidence [2]

- 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.

So, if the CDC’s Rx Guideline is Voluntary . . .

What, Me Worry?
Emerging problems with a “voluntary” guideline and its impact

- Treated as gospel, devil in details
- Politicians and media jumping on the bandwagon
- Misapplication (which was foreseeable):
  - HCPs
  - Regulatory agencies
  - Insurance companies (bonus!)
- See WA state where trigger became ceiling

Ramifications of “accepting” or “rejecting” guidance within the CDC guidelines

- Do not cherry pick. Consider all of them (remember also your state rules and regs remain very important)

- Be clear when you document your rationale.

- Provide a written explanation as to why you chose to deviate from any federal or state “recommendation”
- No martyrs, but be a voice
Summary

- Not a zero sum game: Competing crises
  - Most OD Deaths in MA caused by illegal drugs (8.3% had an Rx; 85% heroin or fentanyl), and most legit pain patients not problem
- Arresting the wrong suspect? Illicit, poly-pharm & substance abuse
- Screening can help reduce potential
- Methadone (2% and 1/3rd). WA ignored at first
- Process, substance, and intrusion concerns.
- Just Say No vs. Just Say Maybe?
- Impact on pain? Misinterpretation, opting out, tapering down
- Hope: CARA (Comprehensive Addiction & Recover Act) (2016)
- Everyone invited and your voice

Thank you for improving people’s lives

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References

References


References

- Ziegler SJ. The proliferation of dosage thresholds in opioid prescribing policies and their potential to increase pain and opioid-related mortality. Pain Med, 2015; 16 (10), 1851-1856.
References

- [http://www.cdc.gov/drugoverdose/prescribing/resources.html](http://www.cdc.gov/drugoverdose/prescribing/resources.html)
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