Summary of the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain



MiCMRC/MiPCT Educational Webinar

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Presenter

- Catherine Reid, MD
- Consulting Physician, Office of Medical Affairs Michigan Dept. of Health and Human Services
- Coordinator for Michigan's Drug Utilization Review Board
 - In her role with MDHHS Catherine reviewing literature regarding best pain management practice, often in coordination with other state Medicaid agencies, formulating policy, prescribing criteria and review of inappropriate controlled substance cases brought by Licensing and Regulatory Agency (LARA), the attorney general's or inspector general's office.
 - As a coordinator on the Drug Utilization Review Board, she reviews prescribing patterns for opiates, opiates and
 concurrent use of benzodiazepines or stimulants, length of short acting opiate use and Morphine Equivalent Daily Dose
 (MEDD) in addition to registering. These reviews resulted in letters to prescribers and changes in Medicaid policy.



Objectives

- Recognize the risk of prescribing opioids
- Understand the key principles and recommendations of the 2016 CDC guideline for assessing and treating a patient with pain
- Understand criticisms of the guidelines and potential impact to patients

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Catherine Reid, MD

Consulting Physician, Office of Medical Affairs Michigan Dept. of Health and Human Services

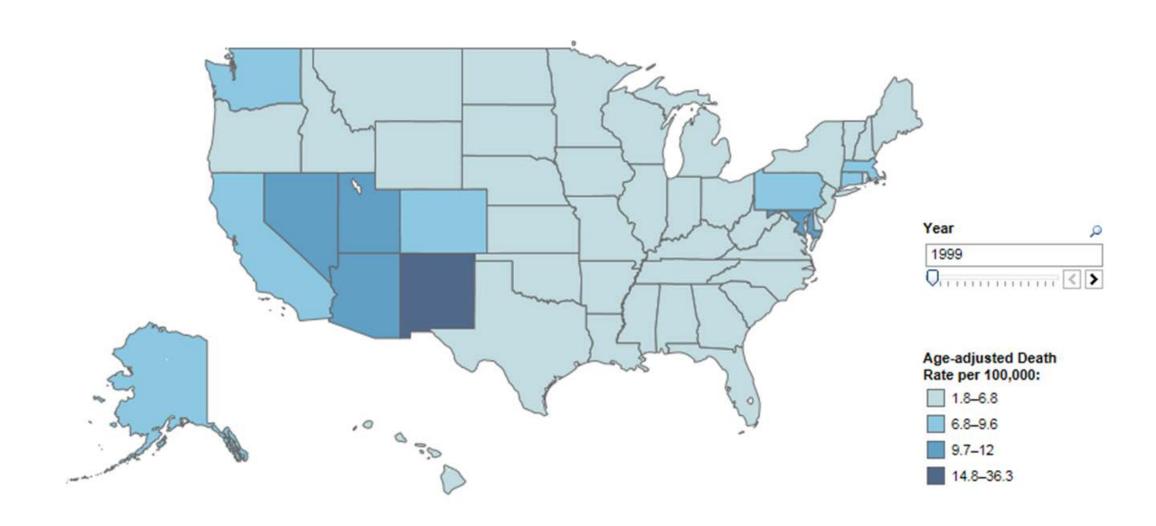
The evolution of our current opioid abuse problem: why the CDC developed guidelines

- Rationale for prescribing pain medications changed in the late 1990s
- Pain was designated as "the 5th Vital Sign" that must be treated
- New extended release opioid drugs were heavily marketed as safer
- Belief that chronic pain can safely be treated without addiction

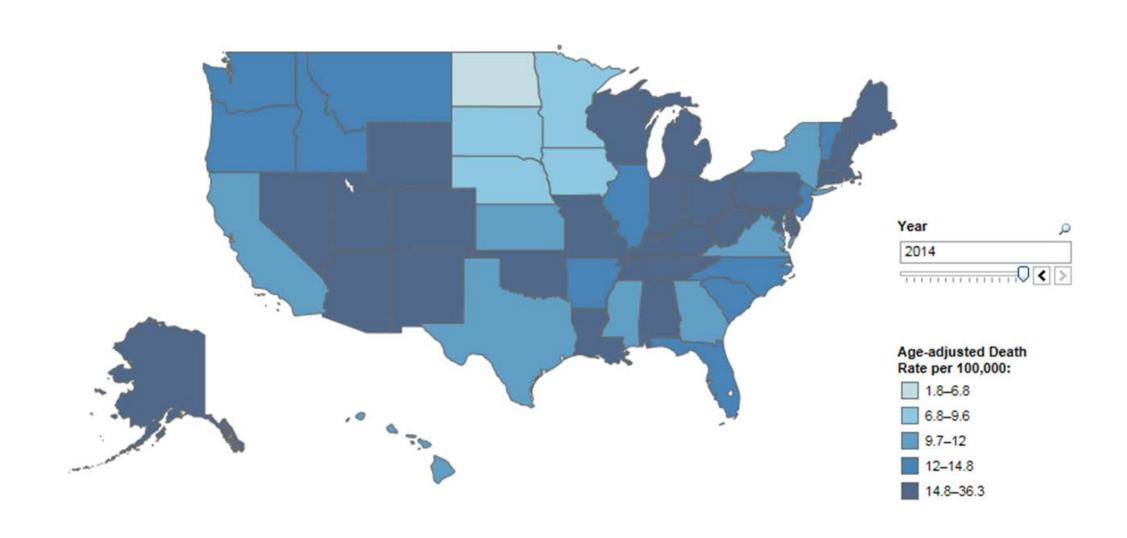
These actions resulted in:

- Widespread prescribing of opioids for routine pain (arthritis, back pain) with high doses and continuous therapy
- Current epidemic of drug abuse and addiction that effects all states, rural and metropolitan areas
- Patients who began abusing prescription drugs often switched to heroin (cheaper) leading to rise in heroin use
- Dramatic rise in misuse, abuse, overdoses and drug related deaths over next ten years

CDC: Death Rates for Drug Poisoning, 1999



CDC: Deaths Rates for Drug Poisoning, 2014



Michigan statistics

| | <u>1999</u> | <u>2014</u> |
|------------------|-------------|-------------|
| Number of deaths | 460 | 1762 |
| State Population | 9,897,117 | 9,909,877 |
| Rate per 100,000 | 4.65 | 18.04 |

Concepts Basic to Pain Management Guidelines:

- Structured approach to patient evaluation: determine correct diagnosis, type of pain, previous treatment, co-morbid conditions and risk of abuse or addiction
- Psychological assessment for co-morbid mood disorders
- Establish treatment goals (increase function should be primary goal)
- Non-pharmacologic and/or non-narcotic treatment modalities first
 - Weight loss
 - Physical therapy
 - Cognitive Behavioral Therapy and Biofeedback techniques

- Non-narcotic modalities
- If narcotics are started, lowest dose on a trial basis should be used
- Frequent reassessment for effect, complications (hyperanalgesia) or abuse
- STOP NARCOTICS IF NO IMPROVEMENT

Morphine Equivalent Dosing

- Converts all opioids to their approximate equivalent in morphine, helps standardize opioid dosing or "Equianalgesic" dose
- Generally expressed as Morphine Equivalent Daily Dose (MEDD)
- Helps when converting one opioid for another
- Dose calculators are widely available
- Example: Oxymorphone 10mg = 30mg morphine

CDC Guidelines, published March 2016

- First federal prescribing guidelines
- Targeted to primary care prescribers (who prescribe half of all narcotics)
- Three key principles and twelve recommendations
- Designed to "support clinicians caring for patients with chronic pain that is <u>outside the context of active cancer treatment, palliative care</u> or end-of-life care".

CDC Guideline development

- Core Expert Group (CEG) and Opioid Guideline Workgroup (OGW)
 whose members provided expert opinion and stakeholder input
- Research to identify high risk prescribing practices
- Defined chronic use as ≥ 3 months
- Reviewed available evidence for prescribing recommendations
- Grading of Recommendations, Assessment, Development and Evaluation (GRADE) method utilized in scientific evidence review *

^{* (}Category A (strongest), B, C or D Recommendations based on Type 1 (strongest), 2, 3 or 4 evidence)

Evidence Reviewed to Answer Five Key Clinical Questions:

- Effectiveness after ≥1 year therapy related to pain, function and quality of live
- Risk of addiction, overdose and other harms and how they vary according to type of pain and dose
- Comparative effectiveness of opioid dosing strategies
- Accuracy of instruments for predicting risk for addiction, abuse or overdose
- Effects of prescribing opioids vs not prescribing for acute pain on long term use

First Key Principle: Determining When to Initiate or Continue Opioids for Pain

1. Nonopioid and Nonpharmacologic therapy is preferred

- Evaluate patient and establish or confirm the diagnosis
- Nonpharmacologic therapy: Physical therapy, weight loss, cognitive behavioral therapy (CBT), interventions (joint injections)
- Nonopioid Rx: NSAIDS, selected antidepressants, anticonvulsants
- Develop patient specific therapy where benefit > risk

2. Before starting opioid therapy, establish realistic treatment goals

- Pain control and improvement in function
- Risk assessment instruments (addiction, co-morbid depression)
- How to discontinue therapy if no meaningful improvement

3. Before starting and periodically during opioid therapy, discuss risks, benefits and responsibilities for managing therapy

- Involve patients in decisions whether to start or continue opioids
- Realistic explanation about long term use and complete relief of pain unlikely
- Emphasize improved function is primary goal
- Advise patient about common (constipation, sedation) and severe side effects (respiratory depression, overdose and addiction)
- Importance of periodic reassessment
- Advise use of precautions to reduce risk (automated prescription drug monitoring systems, random urine drug screens)

<u>Second Key Principle</u>: Opioid selection, Dosage, Duration, Follow-up and Discontinuation

4. Immediate release opioids should be used when starting therapy

- Extended Release (ER) or Long Acting (LA) narcotics (methadone, transdermal fentanyl, ER/LA versions of oxycodone, hydrocodone, morphine) have a higher risk of overdose when initiating treatment
- Abuse-deterrent technologies

5. When opioids are started, lowest effective dose should be used

- Titrate doses to morphine milligram equivalents (MME), calculators available
- Should be < 50 MME/day, Avoid doses ≥ 90 MME/day
- Example: 100mg Oxymorphone/day = 300mg Morphine/day

6. Quantity prescribed: acute pain < 3 days supply, rarely >7 days

- Acute pain severe enough to require opioids
- Long term opioid use can begin with treatment of acute pain

7. Evaluate benefit vs harm in patient within 1-4 weeks of starting opioid therapy

- Evaluate benefits vs harm every 3 months or more frequently for chronic pain or dose escalation
- If benefits < harms, work with patient to optimize other therapies and taper/discontinue opioids

Third Key Principle: Exercise caution when prescribing opioids and monitor all patients closely

8. Before starting and during therapy, evaluate risk factors

- Increased risk: history of overdose, substance use disorder, high opioid dose (> 50 MME/day), concurrent medications (benzodiazepines)
- Incorporate risk mitigation strategies into management plan
- Consider offering naloxone

9. Review patient's history of controlled substance use by using the state's automated prescription drug monitoring system (PDMP)

- In Michigan this is Michigan Automated Prescription System (MAPS)
- Review when starting therapy and during therapy, either every prescription or every 3 months

(Third Key Principle, con't)

- When prescribing opioids for chronic pain, clinicians should use urine drug screens (UDS)
- Ovoid prescribing opioid medications with benzodiazepines
- Offer substance use disorder treatment for patients when needed

Criticisms of the CDC Guideline

- Create unfair hurdles for patients with legitimate pain problems
- Because guideline comes from the CDC, they will not be seen as voluntary but will automatically be followed
- Insurance companies will use them to determine reimbursement
- Even though not intended for cancer or end-of-life, will be applied to these conditions and restrict appropriate care
- Strong recommendations based on low quality scientific evidence

American Medical Association (AMA), Patrice A. Harris, MD

"largely supportive ...we remain concerned about the evidence base informing some of the recommendations, conflicts with existing state laws and product labeling, and possible unintended consequences associated with implementation, which includes access and insurance coverage limitations for non-pharmacologic treatments, especially comprehensive care, and the potential effects of strict dosage and duration limits on patient care"

American Academy of Pain Medicine, Daniel Carr, MD

- "...cautiously supports the efforts of the CDC..."
- "Opioids...are an important option- as part of a comprehensive multidisciplinary approach- that must remain available to physicians and appropriately selected patients."
- "....share concerns voiced by patient and professional groups...that the CDC guidelines makes disproportionately strong recommendations based upon a narrowly selected portion of available clinical evidence."

CDC Response to Critics: Thomas Friedan, MD, MPH and Dr. Debra Houry, MD, MPH in New England Journal Of Medicine, 4/21/2016

- Purpose is for safer, more effective prescribing
- More research/evidence is needed on effectiveness of long term opioid use
- Used rigorous process in evaluating the best available evidence
- Did not find that opioids were better than nonpharmacologic therapies
- ".. for the vast majority of patients, the known, serious, and toooften-fatal risks far outweigh the unproven and transient benefits."

Conclusion

- Pain management is a difficult, complex issue
- CDC attempts to address opioid abuse crisis with guidelines targeted at primary care providers who prescribe half of all narcotics in US
- Treatment may require multiple modalities, some of which may not be readily available or paid for by insurance

- Prescribers and patients must work together to establish realistic goals
- Many professional organizations fear these guidelines, with the weight of the CDC and federal government behind them, will be applied too stringently and reduce care