New Guidelines for Opioid Prescribing

What They Mean for Elders with Chronic Pain

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Starting in the late 1990's, opioid prescribing for chronic pain by U.S. physicians increased dramatically

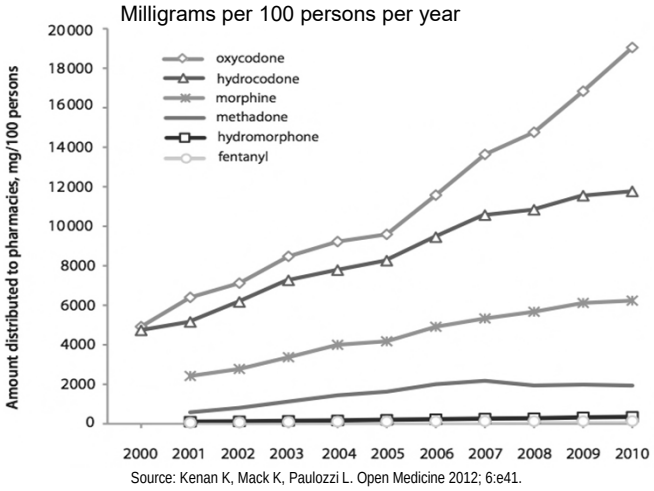
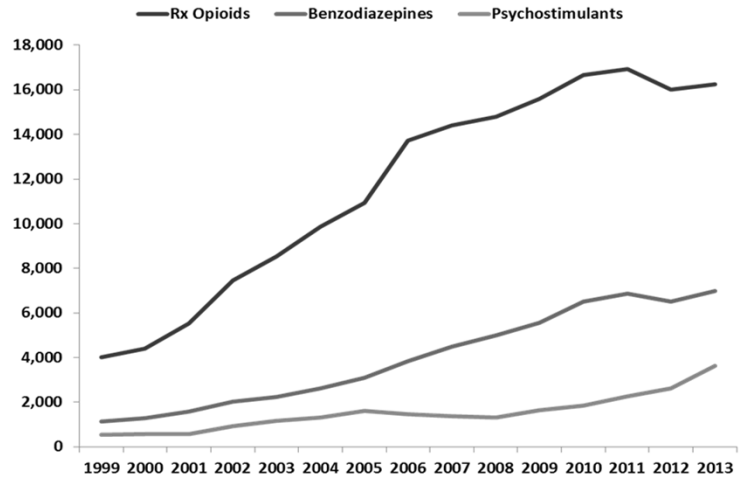


Figure 1
Distribution of selected opioids to US pharmacies (in milligrams per 100 persons). Based on data from the Automation of Reports and Consolidated Orders System, 2000–2010.

Source: Kenan K, Mack K, Paulozzi L. Open Medicine 2012; 6:e41.

This change in practice resulted in a four-fold increase in drug overdose deaths involving prescription opioids

Drug Overdose Deaths, US, 1999-2013



Source: Centers for Disease Control and Prevention, NVSS, 2013

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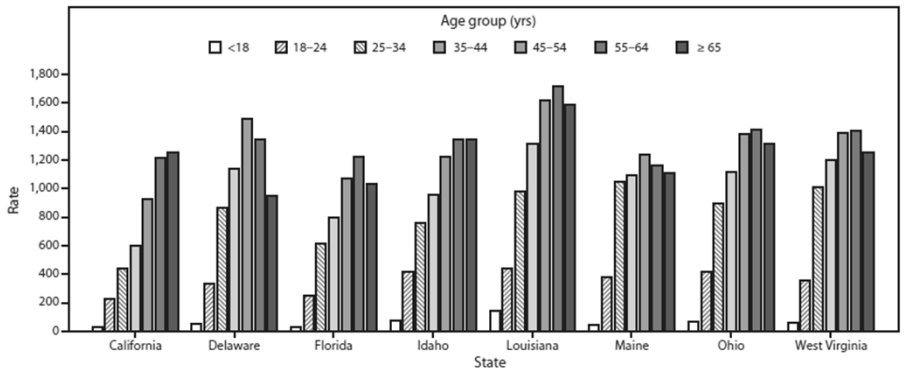
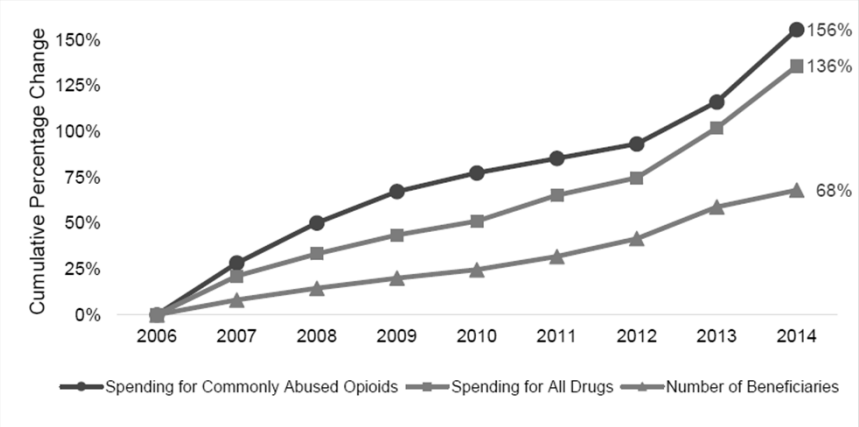


FIGURE 1. Opioid prescribing rates per 1,000 state residents, by age group — Prescription Behavior Surveillance System, eight states, 2013

4

Figure 2: Growth in Spending of Commonly Abused Opioids, 2006–2014



Source: OIG analysis of Medicare Part D data, 2015.

5

Need for Opioid Prescribing Guidelines

- Previous opioid prescribing guidelines have been developed by several states and agencies but were inconsistent
- Most recent national guidelines are several years old and don't incorporate the most recent evidence
- Need for clear, consistent recommendations

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports / Vol. 65 / No. 1 March 18, 2016

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Clinical Review & Education

Special Communication

CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016

Deborah Dowell, MD, MPH; Tamara M. Haegerich, PhD; Roger Chou, MD

IMPORTANCE Primary care clinicians find managing chronic pain challenging. Evidence of long-term efficacy of opioids for chronic pain is limited. Opioid use is associated with serious risks, including opioid use disorder and overdose.

OBJECTIVE To provide recommendations about opioid prescribing for primary care clinicians treating adult patients with chronic pain outside of active cancer treatment, palliative care, and end-of-life care.

PROCESS The Centers for Disease Control and Prevention (CDC) updated a 2014 systematic review on effectiveness and risks of opioids and conducted a supplemental review on benefits and harms, values and preferences, and costs. CDC used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework to assess evidence type and determine the recommendation category.

EVIDENCE SYNTHESIS Evidence consisted of observational studies or randomized clinical trials with notable limitations, characterized as low quality using GRADE methodology. Meta-analysis was not attempted due to the limited number of studies, variability in study designs and clinical heterogeneity, and methodological shortcomings of studies. No study evaluated long-term (>1 year) benefit of opioids for chronic pain. Opioids were associated with increased risks, including opioid use disorder, overdose, and death, with dose-dependent effects.

RECOMMENDATIONS There are 12 recommendations. Of primary importance, nonopioid therapy is preferred for treatment of chronic pain. Opioids should be used only when benefits for pain and function are expected to outweigh risks. Before starting opioids, clinicians should establish treatment goals with patients and consider how opioids will be discontinued if benefits do not outweigh risks. When opioids are used, clinicians should prescribe the lowest effective dosage, carefully reassess benefits and risks when considering increasing dosages to 50 morphine milligram equivalents or more per day, and avoid concurrent opioids and benzodiazepines whenever possible. Clinicians should evaluate benefits and harms of continued opioid therapy with patients every 3 months or more frequently and review prescription drug monitoring program data, when available, for high-risk combinations or dosages. For patients with opioid use disorder, clinicians should offer or arrange evidence-based treatment, such as medication-assisted treatment with buprenorphine or methadone.

CONCLUSIONS AND RELEVANCE The guideline is intended to improve communication about benefits and risks of opioids for chronic pain, improve safety and effectiveness of pain treatment, and reduce risks associated with long-term opioid therapy.

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Deborah Dowell, Tamara Haegerich, and Roger Chou

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Purpose, Use, and Primary Audience

- Primary Care Providers
  - Family medicine, Internal medicine
  - Physicians, nurse practitioners, physician assistants
- Treating patients ≥18 years with chronic pain
  - Pain longer than 3 months or past time of normal tissue healing
- Outpatient settings
- Does not include active cancer treatment, palliative care, and end-of-life care

Organization of Recommendations

The 12 recommendations are grouped into 3 categories:

- Determining when to initiate or continue opioids for chronic pain
- Opioid selection, dosage, duration, follow-up, and discontinuation
- Assessing risk and addressing harms of opioid use

10

Determining when to initiate or continue opioids for chronic pain

11

Recommendation #1: Opioids not first-line therapy

- Nonpharmacologic therapy and nonopioid 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.

(Recommendation category A: Evidence type: 3)

12

Recommendation #2: Establish and measure progress

2

- Establish realistic treatment goals for pain and function
- Before initiating opioid therapy for chronic pain
  - Determine how effectiveness will be evaluated.
  - Establish treatment goals with patients.
    - Pain relief
    - Function
- Assess progress using 3-item PEG Assessment Scale*
  - Pain average (0-10)
  - Interference with Enjoyment of life (0-10)
  - Interference with General activity (0-10)

(Recommendation category A: Evidence type: 4)

13

Recommendation #3: Discuss benefits and harms

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- Be explicit and realistic about expected benefits and patient responsibilities for managing treatment.
- Emphasize goal of improvement in pain and function.
- Discuss serious and common adverse effects
  - increased risks of overdose
    - at higher dosages
    - when opioids are taken with other drugs or alcohol
  - periodic reassessment, PDMP and urine checks; and
  - risks to family members and individuals in the community.

(Recommendation category A: Evidence type: 3)

14

Opioid selection, dosage, duration, follow-up, and discontinuation

15

Recommendation #4: Avoid extended release opioids

- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
- Methadone should not be the first choice for an ER/LA opioid
  - Only providers familiar with methadone's unique risk and who are prepared to educate and closely monitor their patients should consider prescribing it for pain.
- Only consider prescribing transdermal fentanyl if familiar with the dosing and absorption properties and prepared to educate patients about its use.

(Recommendation category A: Evidence type: 4)

16

Recommendation #5: Avoid high dose opioid therapy

- Avoid increasing opioid dosages to ≥90 MME/day.
- If escalating dosage requirements
  - discuss other pain therapies with the patient
  - consider working with the patient to taper opioids down or off
  - consider consulting a pain specialist.
- Offer established patients already taking ≥90 MME/day the opportunity to re-evaluate high dosages in light of the overdose risk.
- For patients who agree to taper opioids to lower dosages, collaborate with the patient on a tapering plan.

(Recommendation category A: Evidence type: 3)

17

Recommendation #6: 3-day supply for acute pain

- Long-term opioid use often begins with treatment of acute pain.
- Prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.
- 3 days or less will often be sufficient; more than 7 days will rarely be needed.
- Do not prescribe additional opioids “just in case”.
- Do not prescribe ER/LA opioids for acute pain treatment.

(Recommendation category A: Evidence type: 4)

18

Recommendation #7: Follow up at least every 3 months

- Re-evaluate patients
  - within 1-4 weeks of starting long-term therapy and at least every 3 months
- At follow up, determine whether
  - opioids continue to meet treatment goals and benefits outweigh risks
  - there are common or serious adverse events or early warning signs
- Work with patients to taper opioids down or off when
  - opioid dosages ≥50 MME/day without evidence of benefit
  - concurrent benzodiazepines that can't be tapered off
  - patients experience overdose, other serious adverse events, warning signs.

(Recommendation category A: Evidence type: 4)

19

Assessing risk and addressing harms of opioid use

20

Recommendation #8: Evaluate risk factors for overdose

8

- Incorporate strategies to mitigate risk
- Avoid prescribing to patients with moderate or severe sleep apnea
- Use additional caution with renal or hepatic insufficiency, aged ≥65 y
- Ensure treatment for depression is optimized.
- Consider offering naloxone when patients
  - have a history of overdose
  - have a history of substance use disorder
  - are taking central nervous system depressants with opioids
  - are on higher dosages of opioids (≥ 50 MME/day).

(Recommendation category A: Evidence type: 4)

21

Recommendation #9: Use Prescription Drug Monitoring Program (PDMP)

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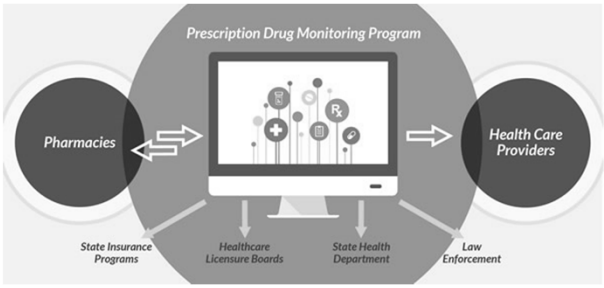

- A prescription drug monitoring program (PDMP) is an electronic database that tracks controlled substance prescriptions in a state. PDMPs can provide health authorities timely information about prescribing and patient behaviors.

22

Recommendation #10: Regular urine drug testing

- At least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
- Don't test for substances that wouldn't affect patient management.
- Before ordering urine drug testing
  - explain to patients that testing is intended to improve their safety
  - explain expected results; and
  - ask patients whether there might be unexpected results.
- Verify unexpected, unexplained results using specific test.
- Do not dismiss patients from care based on a urine drug test result.

(Recommendation category B: Evidence type: 4)

23

Recommendation #11: Avoid opioid with benzodiazepine

- Benzodiazepines are useful for treating insomnia and anxiety, but increases risk of overdose when combined with opioids.
- Taper benzodiazepines gradually.
- Offer evidence-based psychotherapies for anxiety.
  - cognitive behavioral therapy
  - specific anti-depressants approved for anxiety
  - other non-benzodiazepine medications approved for anxiety
- Coordinate care with mental health professionals.

(Recommendation category A: Evidence type: 3)

24

Recommendation #12: Treat opioid use disorder

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.
  - Buprenorphine through an office-based buprenorphine treatment provider or an opioid treatment program specialist
  - Methadone maintenance therapy from an opioid treatment program specialist
  - Oral or long-acting injectable formulations of naltrexone (for highly motivated non-pregnant adults)

(Recommendation category A: Evidence type: 2)

25

Summary

CDC Guideline for Prescribing Opioids for Chronic Pain

Initiate or Discontinue	• Opioids not first-line • Measure progress • Discuss harms and benefits
Opioid Selection and Follow-up	• Avoid extended release opioids • Avoid high dose therapy • 3-day supply for acute pain • Follow-up at least every 3 months
Assess and Reduce Risk for Overdose	• Evaluate risk factors for opioid-related problems • Use PDMP • Regular urine drug screening • Avoid opioids with benzodiazepines • Offer treatment for opioid use disorder

26

What should I do?

- Talk to your doctor about your options
- Be open to trying new evidence-based treatments or considering treatments you haven't tried in a long time
- Take an active role in decision-making and setting treatment goals
- Monitor your own progress
- LOCK UP YOUR SUPPLY!!!
- Never take anyone else's medications or offer to share your medications with anyone. Refer them to the ER!

27

CMS – Opioid Overutilization Monitoring System (OMS)

- In 2013, CMS implemented a two-prong approach to address opioid overuse in Medicare Part D:
  - Plan-level claim controls at point-of-sale (POS) for opioids, i.e. safety edits and quantity limits.
  - Improved retrospective drug utilization review to identify beneficiaries at high risk of an adverse event ("high risk beneficiaries").
  - Case management with the identified beneficiaries' prescribers.
  - Data-sharing regarding identified beneficiary opioid overutilization.
- Starting in 2018, criteria used to define opioid overutilizers have been revised.

28 December 28, 2017

Opioid Overutilizers

- During the most recent six months*,
  - Use of opioids with an average* daily MED equal to or exceeding 90 mg* for any duration, and
  - Received opioids from more than 3 prescribers and more than 3 pharmacies, OR from more than 5 prescribers regardless of the number of dispensing pharmacies.
- Beneficiaries with cancer diagnoses and beneficiaries in hospice are excluded.
- Prescribers associated with a single TIN* are counted as a single prescriber.
- Part D sponsors are provided quarterly reports on high risk beneficiaries and provide CMS with the outcome of their review of each case

29

More to come. . .

- By January 1, 2019, CMS will enforce requirements that the vast majority of prescribers must be enrolled in Medicare for the beneficiaries' drugs to be covered.
  - The Medicare Part D Opioid Prescriber Summary File, presents information on the individual opioid prescribing rates (for new prescriptions as well as refills) of prescribers of Part D drugs.
  - Quarterly Pharmacy Risk Assessment, which categorizes pharmacies as high, medium, or low risk
  - Prescriber Risk Assessment, which provides a peer comparison of Schedule II controlled substance prescribing practices;
  - "Trio Prescriber" initiative, which identifies providers who prescribe combination of an opioid, benzodiazepine, and muscle relaxant
  - Pill Mill Doctor Project identifies prescribers with a high risk of fraud

30 December 28, 2017