Risk Mitigation Strategies to Reduce Opioid Overdoses

Clinician Outreach and Communication Activity (COCA) Call

December 6, 2016

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Planners have reviewed content to ensure there is no bias.

This presentation will include discussion of the unlabeled use of a product or products under investigational use.

Objectives

At the conclusion of this session, the participant will be able to:

- Describe the evidence for opioid prescribing risk mitigation strategies.
- Review different opioid prescribing risk mitigation strategies.
- Summarize steps that clinicians can take when concerning information is discovered through prescription drug monitoring program checks and urine drug testing.
- Evaluate factors that increase risk for opioid overdose and determine when co-prescribing naloxone would be beneficial.

Save-the-Date

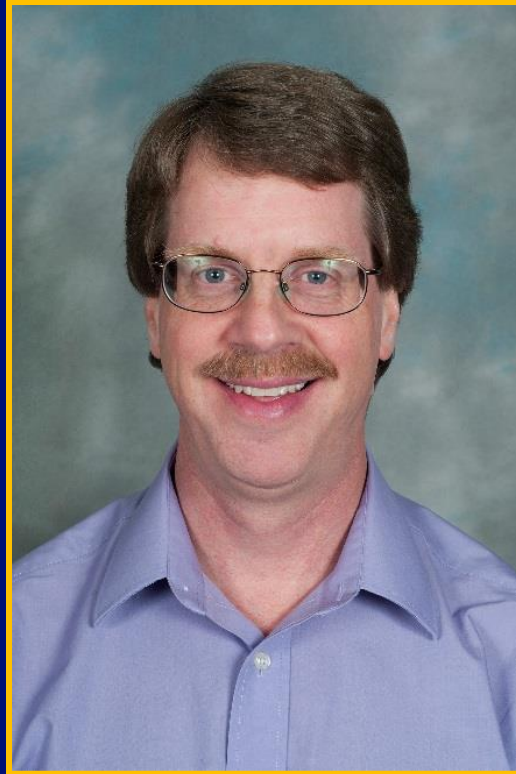
Mark your calendar for the upcoming opioid prescribing call

Date	Topic
December 6	Risk Mitigation Strategies
December 13	Effectively Communicating with Patients about Opioid Therapy

TODAY'S PRESENTER

Deborah Dowell, MD, MPH
Senior Medical Advisor
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

TODAY'S PRESENTER



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TODAY'S PRESENTER

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CDC Guideline for Prescribing Opioids for Chronic Pain:

Risk mitigation strategies: Prescription Drug Monitoring Programs (PDMPs), urine drug testing, and naloxone

Deborah Dowell, MD, MPH

December 6, 2016

MMW

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
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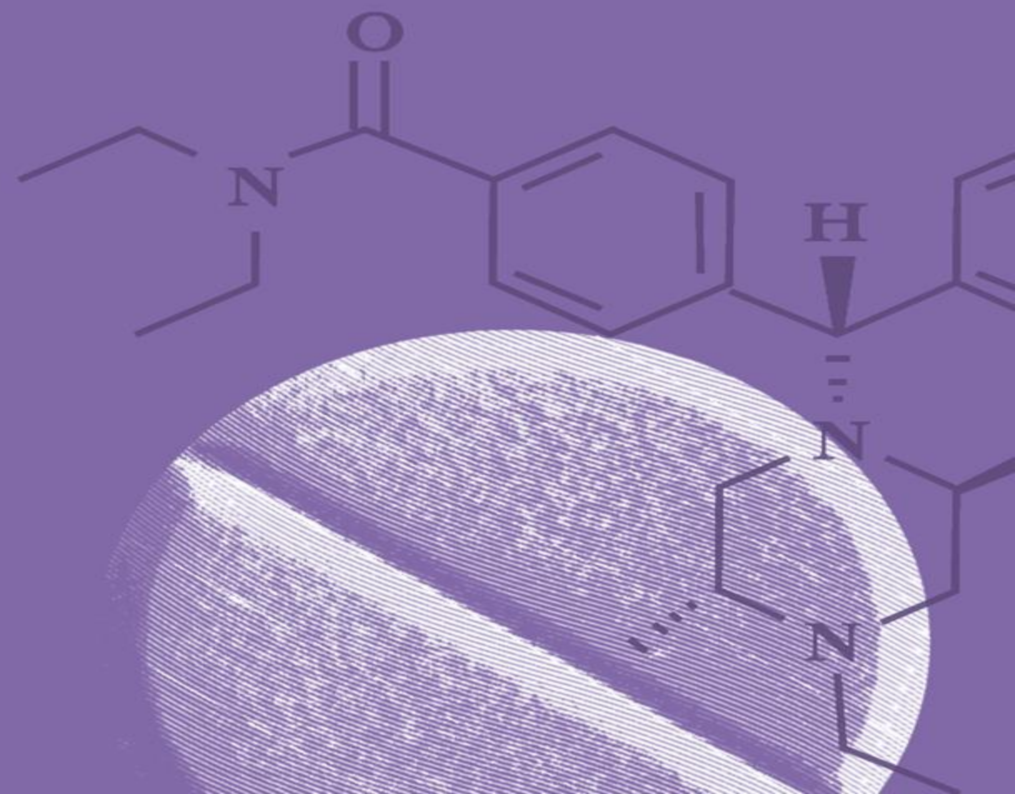

JAMA: The Journal of American Medical Association

Deborah Dowell, Tamara Haegerich, and Roger Chou

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

Published online March 15, 2016

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 dosage 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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Evidence

- Most fatal prescription opioid overdoses associated with*
  - high total daily opioid dosages and/or
  - receiving opioids from multiple sources

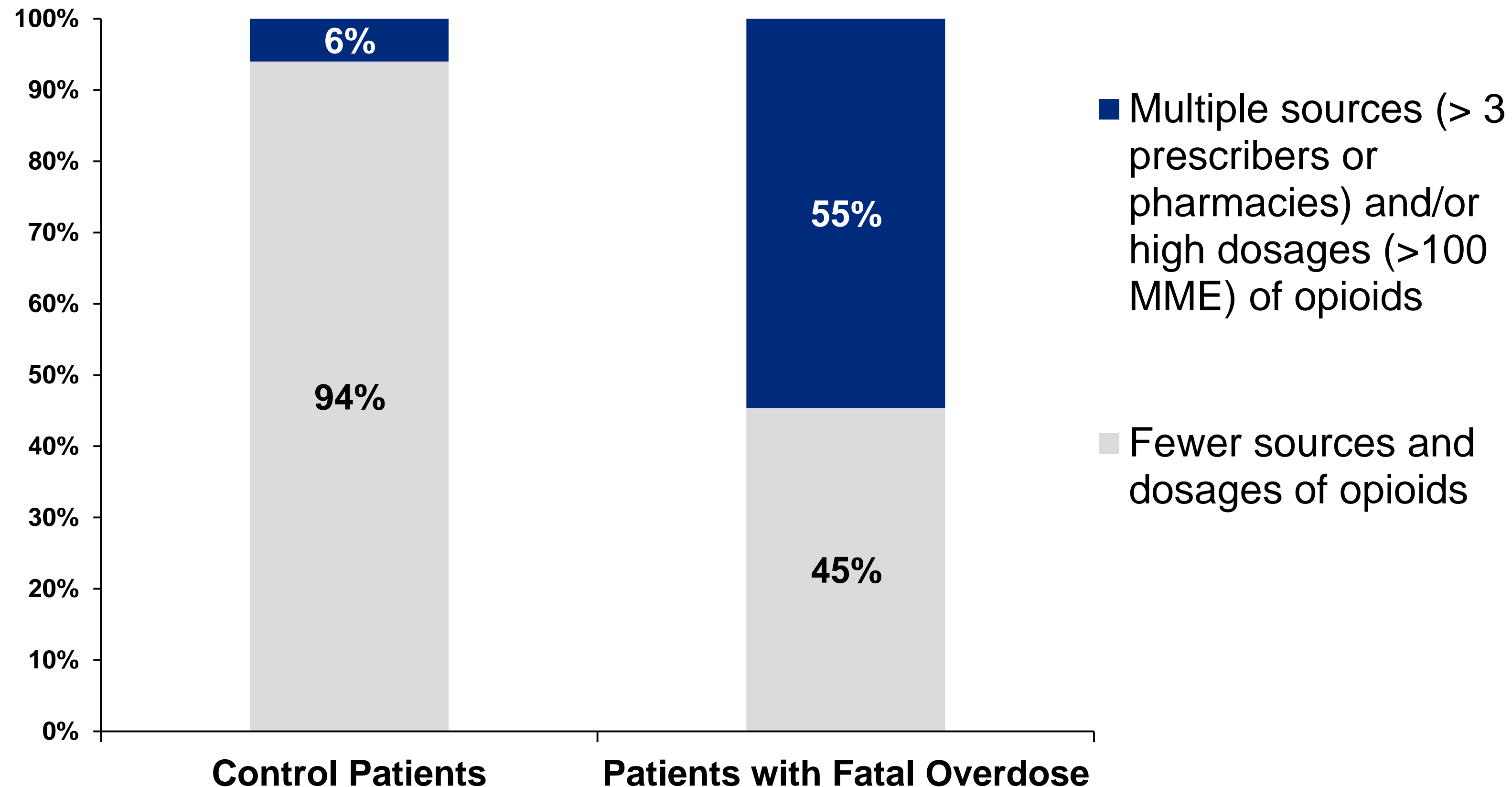
  PDMP provides information on both these risk factors

- Urine drug tests can provide information about drug use that is not reported by the patient

- Naloxone distribution associated with decreased opioid overdose deaths at the community level**

*Gwira Baumblatt et al. High-risk use by patients prescribed opioids for pain and its role in overdose deaths. *JAMA Intern Med* 2014;174:796–801
**Walley AY, Xuan Z, Hackman HH, et al. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. BMJ 2013;346:f174

Most prescription opioid overdose deaths involve multiple sources and/or high dosages



Gwira Baumblatt et al. High Risk Use by Patients Prescribed Opioids for Pain and its Role in Overdose Deaths. *JAMA Intern Med* 2014; 174: 796-801.

Check PDMP for high dosages and dangerous combinations

9

- Clinicians should review the patient's history of controlled substance prescriptions using state PDMP data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him/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.

(Recommendation category A: Evidence type: 4)

If you find concerning information in the PDMP, take action to improve patient safety

- Discuss safety concerns including increased overdose risk
- For patients receiving high total opioid dosages
  - consider tapering to a safer dosage
  - consider offering naloxone
- Consider opioid use disorder and discuss concerns
- If patients are taking benzodiazepines with opioids
  - communicate with others managing the patient
  - weigh patient goals, needs, and risks
- Do not dismiss patients from care—use the opportunity to provide potentially lifesaving information and interventions

PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

EXAMPLE FACT SHEET

WHAT IS A PDMP?

A PDMP is a statewide electronic database that tracks all controlled substance prescriptions. Authorized users can access prescription data such as medications dispensed and doses.

PDMPs improve patient safety by allowing clinicians to:

- Identify patients who are obtaining opioids from multiple providers.
- Calculate the total amount of opioids prescribed per day (in MME/day).
- Identify patients who are being prescribed other substances that may increase risk of opioids—such as benzodiazepines.

WHAT SHOULD I CONSIDER WHEN PRESCRIBING OPIOIDS?

High Dosage

Talk to your patient about the risks for respiratory depression and overdose. Consider offering to taper opioids as well as prescribing naloxone for patients taking 50 MME/day or more.

Multiple Providers

Counsel your patient and coordinate care with their other prescribers to improve safety and discuss the need to obtain opioids from a single provider. Check the PDMP regularly and consider tapering or discontinuation of opioids if pattern continues.

Drug Interactions

Whenever possible, avoid prescribing opioids and benzodiazepines concurrently. Communicate with other prescribers to prioritize patient goals and weigh risks of concurrent opioid and benzodiazepine use.

WHEN SHOULD I CHECK THE PDMP?

State requirements vary, but CDC recommends checking at least once every 3 months and consider checking prior to every opioid prescription.

WHAT SHOULD I DO IF I FIND INFORMATION ABOUT A PATIENT IN THE PDMP THAT CONCERNS ME?

Patients should not be dismissed from care based on PDMP information. Use the opportunity to provide potentially life-saving information and interventions.

1. **Confirm that the information in the PDMP is correct.**
   Check for potential data entry errors, use of a nickname or maiden name, or possible identity theft to obtain prescriptions.
2. **Assess for possible misuse or abuse.**
   Offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients who meet criteria for opioid use disorder. If you suspect diversion, urine drug testing can assist in determining whether opioids can be discontinued without causing withdrawal.
3. **Discuss any areas of concern with your patient and emphasize your interest in their safety.**

Test urine for prescribed opioids and other drugs

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- 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.

(Recommendation category B: Evidence type: 4)

Initial urine drug testing

- Start with an immunoassay panel for
  - prescribed opioids
  - other controlled substances
  - illicit drugs that increase risk for overdose
- Do not test for drugs that would not affect patient management
- Be familiar with testing panels used in your practice and how to interpret results

Discussing urine drug testing with patients

- Explain that drug testing is used to improve safety
- Explain expected results
  - presence of prescribed medication
  - absence of unreported drugs, including illicit drugs
- Ask about use of prescribed and other drugs and if there might be unexpected results
- Provide an opportunity for patients to disclose changes in their use of prescribed opioids or other drugs

Confirming unexpected results

- Discuss unexpected results with
  - Local laboratory or toxicologist
  - Patient
- If unexpected results are not explained, confirm with a selective test such as gas or liquid chromatography/mass spectrometry

Use unexpected results to improve patient safety

- Do not dismiss patients from care based on a urine drug test result
- Consider as appropriate
  - Change in pain management strategy
  - Tapering and discontinuing opioids
  - More frequent re-evaluation
  - Offering naloxone
  - Treatment for substance use disorder

Evaluate and address risks for opioid-related harms

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- 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 ($\geq$50 MME/day), or concurrent benzodiazepine use, are present.

(Recommendation category A: Evidence type: 4)

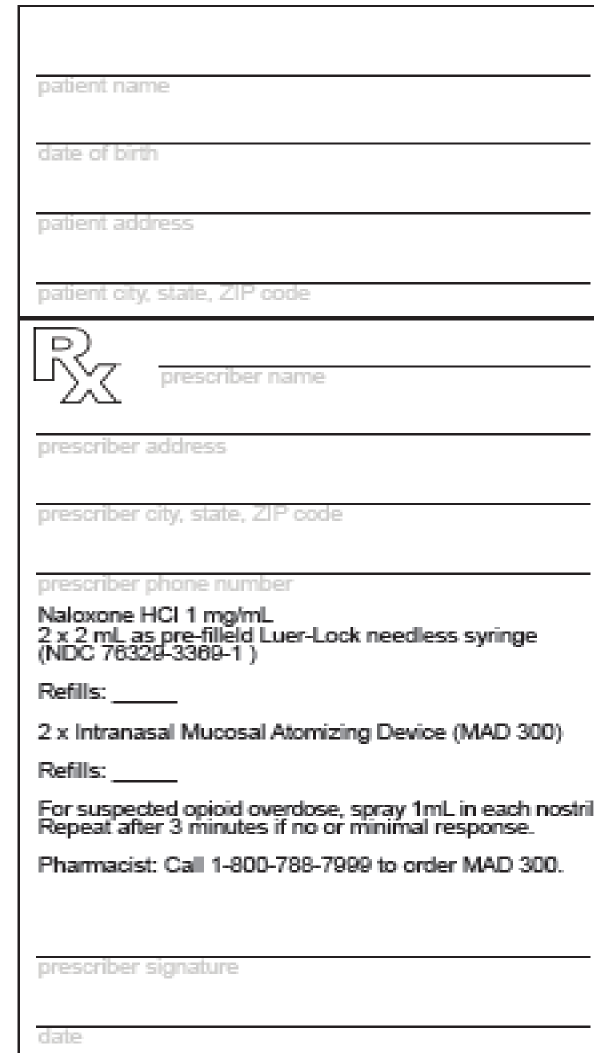
How to prescribe naloxone

- Resources for prescribing naloxone available at http://prescribetoprevent.org
  - Sample prescribing directions
  - Information for patients and their family or household members
  - Information for pharmacists

- Naloxone co-prescribing can be facilitated by collaborative practice models with pharmacists

PRESCRIBE
TO PREVENT

Naloxone for Overdose Prevention



patient name

date of birth

patient address

patient city, state, ZIP code

Rx

prescriber name

prescriber address

prescriber city, state, ZIP code

prescriber phone number

Naloxone HCl 1 mg/mL
2 x 2 mL as pre-fillled Luer-Lock needless syringe
(NDC 76329-3369-1)

Refills: _____

2 x Intranasal Mucosal Atomizing Device (MAD 300)

Refills: _____

For suspected opioid overdose, spray 1mL in each nostril.
Repeat after 3 minutes if no or minimal response.

Pharmacist: Call 1-800-788-7999 to order MAD 300.

prescriber signature

date

Risk mitigation strategies: Prescription Drug Monitoring Programs (PDMPs), urine drug testing, and naloxone

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HARBORVIEW MEDICAL CENTER

DEPARTMENT OF MEDICINE

Risk mitigation strategies: case

- Beth, a 65 year old woman with rheumatoid arthritis and mild joint deformity, who is transferring care due to insurance changes
- Adherent to disease-modifying RA treatment that has been partially effective
- Prescribed #60 oxycodone/acetaminophen 5/325 mg each month for 10 years and denies adverse effects or symptoms of opioid use disorder - total opioid dose 15 mg MED
- Has no prior urine testing, prescription drug monitoring program checks, or controlled substances agreement

Risk mitigation strategy outline

- Prescription drug monitoring programs (PDMP)
- Urine toxicology testing
- Controlled substances agreements

- Apply these strategies in a lower risk case

Strategy: prescription drug monitoring program

- Can identify patients with high risk prescribing
- From a state perspective, can identify very high risk patients who may require specific interventions
- States that require PDMP checks prior to prescribing show reduction in patients with multiple prescribers
- Some evidence that physicians who have access to PDMP data prior to prescribing may prescribe more opioids
- Results may be difficult to interpret

Strategy: prescription drug monitoring program

- Case:
  - Two prescriptions in the past year from a dentist for hydrocodone/acetaminophen 5/325 mg (#10)
  - One prescription from an emergency department visit after an ankle sprain (oxycodone 5 mg #12)
- Opportunity to discuss:
  - Risks of co-prescribing of opioids
  - Potential toxicity of additional acetaminophen
  - Importance of patient reporting outside prescribing
- Document discussion in medical record

Strategy: urine toxicology testing

- Can assist in safety monitoring and diagnosing substance use disorders
- Complex to interpret
  - Screening tests vary in sensitivity and specificity
  - False positive and false negative results are common
  - Patterns of results more important than a single test
  - Best used as a trigger for closer follow up and repeat tests

Strategy: urine toxicology testing - Pitfalls

- Opioids
  - False positive: poppy seeds
  - False negative: oxycodone on opioid screens – need specific test
- Amphetamine/methamphetamine
  - False positive: bupropion, trazodone, decongestants, etc
- Benzodiazepine
  - False positive: sertraline
  - False negative: clonazepam, lorazepam

Strategy: urine toxicology testing

- Case
  - Urine toxicology negative for prescribed oxycodone
  - Specific test also negative
  - Patient reports taking medication prior to activity, not every day
  - Low dose, intermittent use can result in negative tests
- Urine toxicology testing can be useful for safely monitoring and addiction assessment, but many pitfalls
- Discuss unexpected results with the lab you are using, as test characteristics vary

Strategy: controlled substances agreement

- Common approach to informing patients of opioid risks and clinic policies, and anticipating potential problems
- Present rationale as providing informed consent for all patients regarding a potentially risky treatment
- Emphasize no dose escalation without prior consultation – "let me be the doctor"
- Can be coupled with assessment of patient side effects, ranging from sedation to constipation to depression to loss of control

Strategy: controlled substances agreement

- Case:
  - In the last year or two, the patient has noted less energy and more difficulty concentrating later in the day after taking opioids
  - Almost fell after taking two tablets on an especially active day
  - Expresses interest in additional non-medication approaches

Risk mitigation strategies – conclusions

- Important components for monitoring safety of long term opioid prescribing
- Prescription drug monitoring program and urine toxicology checks can be useful, but their limitations must be understood
- Patient education about the risks of prescribing and clinic policies provides an opportunity to avoid problems and reconsider opioid prescribing

Risk mitigation strategies: Prescription Drug Monitoring Programs (PDMPs), urine drug testing, and naloxone

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Safe management of high dose opioid case

- Mr Thomas is a 46 yr old man with low back pain persisting for 8 yrs, and initiated when he was injured at work.
- Apart from back pain, he has no other health issues and takes no medications other than opioids.
- He has not worked since the injury.
- He has some residual low back and left leg pain, and evidence on MRI of slight encroachment of L4 nerve root due to foraminal stenosis.

Safe management of high dose opioid case

- He is not considered a suitable candidate for surgery.
- Epidural steroid injections have provided some relief in the past but he is not interested in receiving any more injections because “it doesn’t last long enough to be worth it”.
- He has tried physical therapy, but feels that it has not helped and he is not willing to try more.
- He takes 30 mg methadone 3 times daily, plus oxycodone IR 10 mg, up to 6 daily
- Total opioid dose 1170mg MMD

Safe management of high dose opioid case

- He has always been a compliant patient, although he has not had a UDT since early in the course of treatment, the PDMP has never been checked, and there is no opioid agreement on file.
- The provider recently learned about the CDC Guideline for Prescribing Opioids for Chronic Pain, and when looking at the CDC's recommendations, realized that his patient was on opioid doses that were no longer considered safe.
- What must the provider do now to improve the safety of the current regime?

First

- Speak to the patient and his family about the new information that has emerged about serious safety considerations related to high dose opioids.
- Explain that new measures need to be taken in order to comply with today's standard of care.
- Explain that one measure will be to gradually taper the opioid to a safer dose, or to discontinuation.
- Explain that the taper can be done slowly so that there is no unpleasant withdrawal, that most people feel better on a lower dose, and that pain relief is not compromised.

First

- Prescribe naloxone and explain to patient and family why this has become necessary, and how and when to use it.

- If the patient is upset, wait until next visit to start the taper.

Second

- *Evaluate for comorbidities that could increase risk*

Comorbidities	***Recommended actions***
Depression or anxiety	Counseling and possible medication
PTSD or history of abuse/trauma	Consider psychiatric referral
Poor sleep	Consider sleep study, teach sleep hygiene
Sleep apnea	Consider formal assessment and treatment
Obesity	Consider nutritional consult
Constipation	Treat with diet, stool softener and gentle laxative
Risk of misuse or abuse	Get baseline from opioid risk screener
Cognitive impairment	Screen for reaction times, discuss driving risks
Dementia	Protect against falls
Medication issues	CNS depressants, anticholinergics

Third

- Get a baseline UDT
- Check the PDMP
- Write up a goal directed opioid agreement and explain why it is needed

Fourth

- Explain tapering options:

  1) Slow taper starting with either long acting or short acting (not both)
  2) Rapid taper with suboxone induction (not option if tapering methadone)
  3) Adjuncts for depression or anxiety during taper (eg small dose of TCA)
  4) If also on a benzodiazepine, choose between opioid and benzodiazepine

Fifth

Depending on results of UDT, PDMP and medical evaluation, decide upon:

- speed of taper
- possible need for immediate discontinuation (rare, only if needed for safety)
- future frequency of provision of prescriptions
- UDT schedule
- PDMP review schedule
- need for additional providers (eg psychology/psychiatry, PT, group therapy)

Fifth

- If addiction is diagnosed, refer for addiction treatment and do not prescribe opioids for pain once addiction treatment is started. Continue treating pain using non-opioid modalities.

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  - "Click" the Q&A tab at the top left of the webinar tool bar
  - "Click" in the white space
  - "Type" your question
  - "Click" ask

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  - State your name
  - Listen for the operator to call your name
  - State your organization and then ask your question

Thank you for joining!

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When: A few days after the live call

What: All call recordings (audio, webinar, and transcript)

Where: On the COCA Call webpage

http://emergency.cdc.gov/coca/calls/2016/callinfo_112916.asp

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Guideline for Prescribing Opioids for Chronic Pain Call Series

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Date	Topic
June 22	Guideline for Prescribing Opioids for Chronic Pain
July 27	Non-Opioid Treatments
August 3	Assessing Benefits and Harms of Opioid Therapy
August 17	Dosing and Titration of Opioids
November 29	Assessment and Evidence-based Treatments for Opioid Use Disorder

Upcoming COCA Call
registration is not required

Gearing up for the Travel Season: How Clinicians Can Ensure Their Patients are Packed with Knowledge on Zika Prevention

- **Date: Thursday, December 8, 2016**
- **Time: 2:00 – 3:00 pm (Eastern)**
- **Presenters:**
  - Dr. Mary Tanner – CDC
  - Dr. Allison Taylor Walker – CDC

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