2016 CDC Guidelines for Opioid Prescribing

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Disclosures

- David A Edwards has documented that he has nothing to disclose.

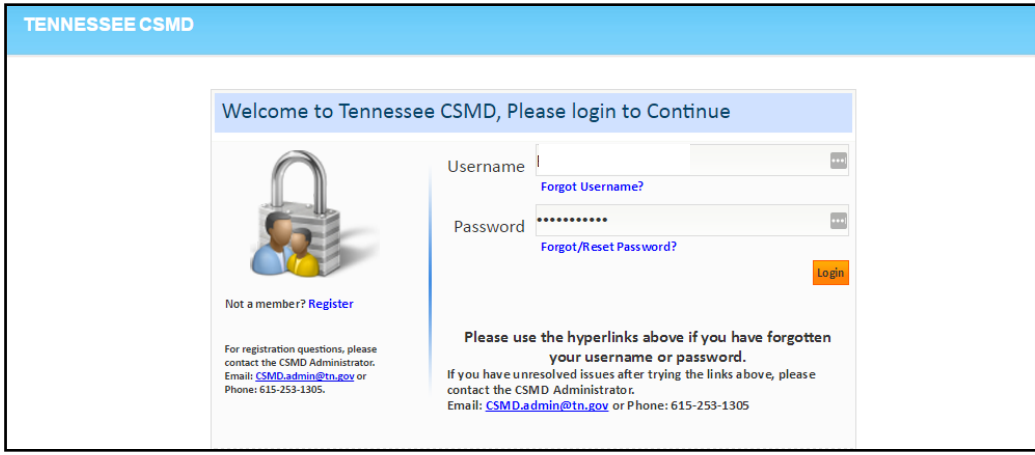
- This presentation does not contain off-label or investigational use of drugs or products.

Introduction

Objectives

1. To be able to list the 12 CDC Guidelines for prescribing Opioids

2. To know how to prescribe controlled substances and remain compliant



Opioid Guidelines

Federal

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

- ~20% of patients visiting a Dr.'s office with pain are prescribed an opioid (1)
- ~14% of adults have chronic pain (7)
- 165,000 overdose deaths in 1999-2014 (16)
- 420,000 ED visits for opioid misuse in 2011 (19)
- Opioid Use Disorder (DSM-IV) – 1.9 million

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

- 1 in 550 patients with cancer died from opioid O.D. at median 2.6 years (21)

- 1 in 32 at doses > 200 MME

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

1. Evaluate benefits and harms within 1 to 4 weeks of starting opioids, and every 3 months
2. Incorporate strategies to mitigate risk, offer naloxone when history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepines
3. Review PDMP data when starting opioids and every 3 months
4. Use urine drug testing at least annually
5. Avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible
6. Offer or arrange treatment for patients with opioid use disorder
7. Nonpharmacologic, nonopioid are preferred . If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy
8. Before starting opioids, establish treatment goals, consider how opioid therapy will be discontinued, and continue opioid therapy only if there is clinically meaningful improvement in pain and function
9. Discuss with patients known risks and realistic benefits and patient and clinician responsibilities
10. Prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids
11. Prescribe the lowest effective dosage, and carefully reassess when increasing to ≥50 MME/day, and avoid or carefully justify a decision to titrate dosage to ≥90 MME/day
12. For acute pain, prescribe the lowest effective dose of immediate-release opioids, no greater quantity than needed for expected duration of pain, three days or less; > seven days rarely needed

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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)

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

1

Nonpharmacologic, nonopioid are preferred . If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy.

2

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 (recommendation category: A, evidence type: 4)

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

1. **Nonpharmacologic, nonopioid are preferred . If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy.**

2. **Before starting opioids, establish treatment goals, consider how opioid therapy will be discontinued, and continue opioid therapy only if there is clinically meaningful improvement in pain and function.**

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 (recommendation category: A, evidence type: 3).

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

1. **Nonpharmacologic, nonopioid are preferred . If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy.**

2. **Before starting opioids, establish treatment goals, consider how opioid therapy will be discontinued, and continue opioid therapy only if there is clinically meaningful improvement in pain and function.**

3. **Discuss with patients known risks and realistic benefits and patient and clinician responsibilities.**

4. When starting opioid therapy for chronic pain, clinicians **should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids** (recommendation category: A, evidence type: 4).

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

1. **Nonpharmacologic, nonopioid are preferred . If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy.**

2. **Before starting opioids, establish treatment goals, consider how opioid therapy will be discontinued, and continue opioid therapy only if there is clinically meaningful improvement in pain and function.**

3. **Discuss with patients known risks and realistic benefits and patient and clinician responsibilities.**

4. **Prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids**

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 (recommendation category: A, evidence type: 3).

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

1. **Nonpharmacologic, nonopioid are preferred . If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy**

2. **Before starting opioids, establish treatment goals, consider how opioid therapy will be discontinued, and continue opioid therapy only if there is clinically meaningful improvement in pain and function**

3. **Discuss with patients known risks and realistic benefits and patient and clinician responsibilities**

4. **Prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids**

5. **Prescribe the lowest effective dosage,** and **carefully reassess when increasing to ≥50 MME/day**, and **avoid or carefully justify a decision to titrate dosage to ≥90 MME/day**

6. 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 seven days will rarely be needed** (recommendation category: A, evidence type: 4).

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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 (recommendation category: A, evidence type: 4).

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Evaluate benefits and harms within 1 to 4 weeks of starting opioids, and **every 3 months.**

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 (recommendation category: A, evidence type: 4).

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

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Evaluate benefits and harms within 1 to 4 weeks of starting opioids, and **every 3 months**

Incorporate strategies to mitigate risk, **offer naloxone** when **history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day),** or **concurrent benzodiazepines**

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 (recommendation category: A, evidence type: 4)

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

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7 **Evaluate benefits and harms within 1 to 4 weeks of starting opioids,** and **every 3 months**
2
8 **Incorporate strategies to mitigate risk**, **offer naloxone** when **history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day),** or **concurrent benzodiazepines**
3
9 **Review PDMP data when starting opioids and** every 3 months
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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).

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

7 **Evaluate benefits and harms within 1 to 4 weeks of starting opioids,** and **every 3 months**

8 **Incorporate strategies to mitigate risk**, **offer naloxone** when **history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day),** or **concurrent benzodiazepines**

9 **Review PDMP data when starting opioids and** every 3 months

10 **Use urine drug testing at least annually**

11 Clinicians should **avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible** (recommendation category: A, evidence type: 3).

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

7. **Evaluate benefits and harms within 1 to 4 weeks of starting opioids,** and **every 3 months**

8. **Incorporate strategies to mitigate risk**, **offer naloxone** when **history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day),** or **concurrent benzodiazepines**

9. **Review PDMP data when starting opioids and** every 3 months

10. **Use urine drug testing at least annually**

11. **Avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible**

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** (recommendation category: A, evidence type: 2).

Opioid Laws

Federal

Federal Opioid Prescribing Laws

2016 - **House Passes Numerous Opioid-Abuse Deterrent Bills**

H.R. 4978 – NAS Healthy Babies Act – click here
H.R. 3680 – Co-Prescribing to Reduce Overdoses Act of 2016 – click here
H.R. 3691 – Improving Treatment for Pregnant and Postpartum Women Act of 2016 – click here
H.R. 1818 – Veteran Emergency Medical Technician Support Act of 2016 – click here
H.R. 4969 – John Thomas Decker Act of 2016 – click here
H.R. 4586 – Lali's Law – click here
H.R. 4599 – Reducing Unused Medications Act of 2016 – click here
H.R. 4976 – Opioid Review Modernization Act of 2016 – click here
H.R. 4982 – Examining Opioid Treatment Infrastructure Act of 2016 – click here
H.R. 4981 – Opioid Use Disorder Treatment Expansion and Modernization Act – click here
H.R. 5046 – The Comprehensive Opioid Abuse Reduction Act – click here
H.R. 5052 – The Opioid Program Evaluation Act – click here
H.R. 5048 – The Good Samaritan Assessment Act of 2016 – click here
H.R. 4985 – The Kingpin Designation Improvement Act of 2016 – click here
S. 32 – Drug Trafficking Act of 2015 – click here

Federal Opioid Prescribing Laws

Government to establish laws to prevent:

- Abuse
- Trafficking
- Diversion

Federal Opioid Prescribing Laws

Government to establish laws to prevent:

...while balancing the need to ensure availability for medical and scientific use

- Abuse
- Trafficking
- Diversion

Federal Opioid Prescribing Laws

Prescribers must obey **federal** and **state** laws.

Federal Opioid Prescribing Laws

Prescribers must obey **federal** and **state** laws.

What if they differ?

Prescribers should practice by the most stringent rule

Federal Opioid Prescribing Laws

Controlled Substances Act (CSA), 21 USC 801-890

DEA regulations, Title 21, Code of Federal Regulations (CFR), Parts 1300 to 1316

01 Manner of issuance of prescriptions. (a) **All prescriptions** for controlled substances shall be **dated as of, and signed on, the day when issued** and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address, and registration number of the practitioner" (21 CFR, Section 1306.05).

02 According to federal law, **a prescription** for a controlled substance **must include the following** information (21 CFR 1306.05[a]):

Date of issue
Patient's name and address
Practitioner's name, address, and DEA registration number
Drug name
Drug strength
Dosage form
Quantity prescribed
Directions for use
Number of refills (if any) authorized
Manual signature of prescriber

Federal Opioid Prescribing Laws

Controlled Substances Act (CSA), 21 USC 801-890

DEA regulations, Title 21, Code of Federal Regulations (CFR), Parts 1300 to 1316

03 …. the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding **liability rests upon the pharmacist**, including a pharmacist employed by a central fill pharmacy, **who fills a prescription not prepared in the form prescribed** by DEA regulations" (21 CFR 1306.05).

04 The Narcotic Addiction Treatment Act of 1974 and the Drug Addiction Treatment Act of 2000 amended the CSA with respect to the use of controlled substances in the medical treatment of addiction. Practitioners wishing to administer and dispense approved Schedule II controlled substances (that is, methadone) for maintenance and **detoxification treatment must obtain a separate DEA registration** as a Narcotic Treatment Program.

Federal Opioid Prescribing Laws

Can I discharge an addict with opioids after surgery?

Federal Opioid Prescribing Laws

Controlled Substances Act (CSA), 21 USC 801-890

DEA regulations, Title 21, Code of Federal Regulations (CFR), Parts 1300 to 1316

05 Federal law **does not prohibit** prescribing, dispensing, or **treating a narcotic addicted patient** with controlled substances as long as the purpose is for alleviating pain and not treatment of addiction.

The DEA does not limit a physician from treating (**NOT prescribing**) a patient with controlled substances in a hospital for maintenance or detoxification as an incidental adjunct to other treatments.

06 Treatment of addiction requires licensure to dispense controlled substances for this purpose (Office of National Drug Control Policy Reauthorization Act of 2006): up to 100 patients at a time.

Federal Opioid Prescribing Laws

Controlled Substances Act (CSA), 21 USC 801-890

DEA regulations, Title 21, Code of Federal Regulations (CFR), Parts 1300 to 1316

07

1306.07 – Narcotic dependent patient:

Can **administer** (not prescribe) **a narcotic drug to relieve acute** withdrawal while arranging for an opioid treatment program.

- One day at a time
- Up to 3 days
- No renewals or extensions

Summary

1. Federal Laws follow guideline and policy decisions – understand the CDC's 12 guidelines

2. High dose opioid prescribing gradually being constrained to specialists

3. Perioperative clinicians can treat addicts in the course of managing pain, but cannot recommend longer than 7 days post-discharge opioid treatment in many instances (law is vague).

Thank-you